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MARYLAND
Pharmacist

Volume 74, No. 1

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DIRECTOR'S COLUMN

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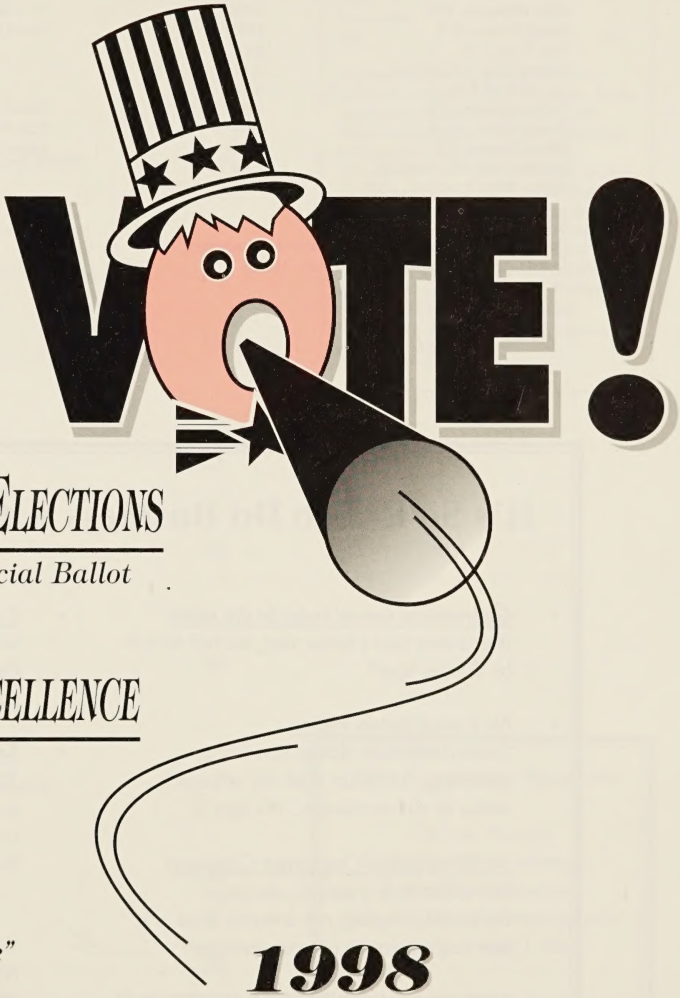
CONTINUING EDUCATION

"Clinical Aspects of Antihistamine Use"



1998
MPhA Elections

MARYLAND PHARMACISTS ASSOCIATION

Jan./Feb./Mar. 199

Maryland Pharmacists Association
650 W. Lombard Street
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(410) 727-0746

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1/98

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President's Commentary

"We've Taken the Plunge"

Jean Freels, P.D.
President

It seems as though time passes quickly between issues of this journal. I find it hard to believe that my term is more than half over. As I sat down to prepare this article, I reflected on the past six months. One thought that came to mind is - change is a lot of hard work! This concept is paralleled in my everyday practice as well as my association work. Although the basic concept of pharmacy remains the same, helping patients by providing quality pharmacy care. The specific route to accomplish this task seems to change on a daily basis. Pharmacists are often busy maintaining themselves on the continuum of change. Consequently, it's more difficult supporting a profession that itself is in transition. It is during this transitional phase, however, that we can affect the most change.

Although we have not accomplished what I had envisioned at the onset of my term, I feel we have made a fine start to many important changes.

"We've taken the plunge." We have committed ourselves to encompassing new ideas, and responding to the needs of our membership. The association internally has also experienced a great amount of change. Not only have we had two new executive directors, but also three new staff personnel in the past two years. This may have slowed the association's progress initially, but has been an enormous benefit long-term. Our new staff each have brought an energetic and objective breath of fresh air to our association. The association staff, officers, and trustees work behind the scenes to support you and your profession. The association acts as pharmacists' advocates in several arenas. What we probably haven't done enough of is getting the message out about all that we do. But when I thought about it, that is a typical response of a pharmacist. After all, we don't run out to a patient waving a banner stating that we potentially just saved their life. Instead, we simply resolve the situation whether it is a drug interaction, or a dosing error and move onto the next patient. Likewise, the association doesn't issue a press release every time they affect a positive change within our profession. The association does report its activities through our newsletters and journals. Members need to stay informed and support our efforts. Two areas where members need to take an active role are elections of officers and trustees, and legislation. It is your responsibility as a MPhA member to vote. Secondly, the legislative session is in full swing. Our members must be aware of legislation that affects our profession. Nothing could potentially hinder our progress legislatively more, than a legislator receiving an uninformed or uninterested response from a pharmacist when called upon to give their opinion. Let us all do our part to make pharmacy and our association to be proud of in the years to come.

If Winter Comes, Can Spring and Media Campaigns Be Far Behind?

Robert J. Boerner
Executive Director

We have reached that time of year when the holidays are over, and we have to face at least several weeks of winter before spring begins to open buds, hearts and doors. It is a time when many of us long for that winter break in warmer climates. Others, who are winter sports enthusiasts -- especially skiers, may think twice about escaping to their usual haunts this year. In the midst of this seasonal slump we need something to lift our spirits.

What could be more appropriate to do than a media campaign to "promote the role of the pharmacist" in the state of Maryland. More specifically, a campaign to promote the role of the pharmacist as a health care provider. The Maryland Board of Pharmacy has signed a contract with MMA Public Relations and Advertising Company to provide technical guidance for the promotion. I was asked to join the Oversight Committee which will advise on what concepts will work best in different types of media. The Oversight Committee is expected to meet seven times between January and June 1998.

I attended the first meeting on January 8 where we heard a history of the project and discussed the role of the Oversight Committee. Topics covered included the need to promote the pharmacist as a health care provider, the possibility of radio and TV public service announcements, print articles, a brochure and a poster. The Poison and Information Center will to have a high profile in the campaign because it provides an important community service. Fund raising and the need to increase the number of calls to the Poison and Information Center will be important aspects of the media campaign. In order to increase community awareness of the Poison and Information Center, we must reach those who are most likely to need its services--parents of children age six or under, through day care centers, churches, community organizations, schools, educators, hospital maternity wards and pharmacies. I made the point that the campaign needed to identify ways to bring people to pharmacies for health care service information with a minimum of interference to the heavy work schedules of the pharmacists.

The Oversight Committee has broad representation from pharmacy and the community. Its members include the Board of Pharmacy, the Poison and Information Center, the University of Maryland, the Maryland Society of Hospital Pharmacists, the University of Maryland School of Pharmacy, MMA Public Relations and Advertising Company, community representatives and the Maryland Pharmacists Association. The only other thing the Oversight committee could benefit from is input from Maryland pharmacists about what they would like to see this campaign focus on. You are the ones being promoted. How should we do it? Where should we do it? How would you like us to portray you? What role should you play in the promotion? What materials should be made available to you to promote yourselves?

The planning phase will end in early spring, and the implementation phase will begin. I would very much like to hear from you about your thoughts on the above questions before spring ends our winter doldrums.

1998-99 Association Officers

The MPhA Board of Trustees approved the slate of nominees presented at the House of Delegates Session held on February 28, 1998 at the Sheraton, Towson. A call for additional nominations was made at the Delegates Session, and the slate determined by the House is before the members for voting. Profiles of the nominees and a ballot is included in this issue of the *Maryland Pharmacist.* The slate of candidates presented is as follows:

President-Elect - Joe DeMino, P.D. and Rhea-Marie del Rosario, R.Ph.
Vice-President - Robert Martin, Jr., P.D. and Joe Marrocco, P.D.
Treasurer - Lance Berkowitz, P.D.
Candidates for Trustee Seat #1 - Richard Baylis, C.G.P. and Douglas Haggerty, P.D.
Candidates for Trustee Seat #2 - Alisa Billington, P.D. and Lynette Bradley, P.D.
Candidates for Trustee Seat #3 - Steven Disharoon, P.D. and Gary Hass, R.Ph.
Candidates for Trustee Seat #4 - Marcus Carson, P.D. and Scott Kuperman, P.D.

The officers and trustees make the decisions which govern the direction of the Association. In this crucial period facing the profession, good leadership is important. ***Don't forget to vote!***

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1931 - William B. Spire
1930 - L. S. Williams
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1928 - Howell W. Allen
1927 - Harry R. Rudy
1926 - H. A. B. Dunning
1925 - S. Y. Harris
1924 - W. K. Edwards
1923 - C. L. Meyer
1922 - A. L. Lyon
1921 - R. E. L. Williamson
1920 - G. E. Pearce
1919 - D. R. Millard
1918 - W. H. Clarke
1917 - Eugene W. Hodson
1916 - Thomas Williamson
1915 - George A. Bunting
1914 - J. F. Leary
1913 - J. Fuller Frames
1912 - D. P. Schindel
1911 - James E. Hancock
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1886 - A. J. Corning
1885 - E. Eareckson, M.D.
1884 - D. C. Aughinbaugh
1883 - J. J. Thomsen

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidates for President-Elect

Rhea-Marie del Rosario, R. Ph.
1203 Sabina Avenue
Baltimore, MD 21209

University of Maryland School of Pharmacy
Graduation Year: 1995
Practice: Retail
Employer: Horizons Professional Pharmacy/EPIC

If elected to this position, I will devote my time and energy to provide guidance as the MPhA meets challenges to the 21st century. These challenges include pharmaceutical care, managed care, and collaborative practice, just to name a few. We must aggressively demonstrate that the cognitive services we employ daily are paramount for positive outcomes for all parties involved.

Presently, I serve as Vice-Speaker of the MPhA House. In addition, I served as Trustee for two previous terms, one of which I was a student as A.S.P. president. This early involvement was an awakening to the significance of the MPhA to pharmacists and pharmacy students.

With the rapid changes in health care, a strong association is critical to the protection and preservation of our profession. It would be of great privilege and honor to continue to serve you as we move forward into the 21st century. Thank you for your consideration and support.

Joseph A. DeMino, P.D.
410 Midsummer Drive
Gaithersburg, MD 20878

University of Maryland School of Pharmacy
Graduation Year: 1984
Practice: Chain Community Pharmacy
Employer: CVS Pharmacy

I look forward to the honor and privilege of serving the profession of pharmacy and the state of Maryland as President of the Maryland Pharmacists Association.

I have spent my entire adult life in the practice of pharmacy. During my school years and after graduating from the University of Maryland School of Pharmacy in 1984 I have been actively involved with MPhA. I have served on numerous committees, in the House of Delegates and as a member of the Board of Trustees. I was previously Vice-Speaker of the House and currently serve as Speaker of the House of Delegates.

My experience in working with the current Board of Trustees and officers has been extensive. The experience will enable me to assist in the continuing progress of our profession and our avocation.

Pharmacy continues to undergo dramatic change in education, technology, regulation, and the expanded role of the Pharmacist in patient care. These changes in pharmacy require that all levels of pharmacy practice work together to strengthen our role as health care providers in the Health Care System today and in the future.

My experience, my commitment of time and energy will enable me to contribute to the strength of our profession and our association.

I ask for and appreciate your support.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidate for Vice-President

Robert J. Martin, Jr., P.D.
852 Camden Avenue
Cumberland, MD 21502

University of Maryland School of Pharmacy
Graduation Year: 1974
Practice: Independent Community Pharmacy
Employer: Potomac Valley Pharmacy, Inc.

I am a life long resident of Cumberland, Maryland. I graduated in 1974 from the University of Maryland School of Pharmacy. For the past 23 plus years I have been involved with the operation of Potomac Valley Pharmacy, Inc., a two-store, family owned community pharmacy. I had also been very active in home medical equipment, home respiratory and home infusion. Since January 1997, I have managed the local branch of American Home Patient providing the aforementioned services as well as operating Potomac Valley Pharmacy, Inc.

I have served on the MPhA Board of Trustees for six years and would like to continue serving the organization as Vice-President. I believe with my background, both in the practice of pharmacy and related health care settings, I can make a positive contribution to all of the pharmacists of Maryland. Thank you for your consideration.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidate for Vice-President

Joseph Marrocco, P.D.
3909 Eland Road
Phoenix, MD 21131

Duquesne University School of Pharmacy
Graduation Year: 1973
Practice: Pharmacy Development Manager
Employer: Rite-Aid Pharmacies

If elected to this position of Vice-President, I will devote my focus and energy to enable MPhA to *"Chart"* the course, not merely to follow it, as changes continue to impact our pharmacy profession.

I have been honored to serve you and MPhA three prior terms - presently as Vice-President and prior as Speaker and Vice-Speaker of the House of Delegates. These positions enabled MPhA to "team" on a number of important issues that reflect us all. I present to you my near perfect meeting attendance, work with the yearly terms of six diligent, dedicated presidents of your fine state association, whom like I, volunteer their time to keep our association at the forefront of pharmacy matters where/whenever applicable.

Presently, I also serve as Co-chairman of the Building and Property Committee, a responsibility I have accepted for the past several years. The focus of my energy in this committee is immediate and urgent, as we are in the midst of information gathering and discussion with our legal counsel, committee members, and the Board to determine and finalize what location and building structure at the University of Maryland Medical System and Professional Schools campus would best serve our MPhA members for the present and also the years to come.

As a Pharmacy Development Manager, I recognize and share your concerns of third parties, prescription benefit managers, and drug manufacturers. My goal, like yours, is to continue to strive to have pharmacists compensated for our knowledge. Continued widespread efforts and recognition for our "cognitive services" is paramount in my sphere of thinking.

In final analysis, I pledge to you, my fellow pharmacists of all spheres of practice, an open-door policy that is reflective and responsive to your concerns in your daily practice setting. I would welcome routinely your feedback and ideas of where our association should be pointing, and the course it should be "charting."

As your elected leader, I feel this mission is paramount and vital to us all. Thank you for your consideration and support. I would be honored to serve you and our most trusted profession or pharmacy.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidate for Treasurer

Lance Berkowitz, P.D.
3801 Canterbury Road #802
Baltimore, MD 21218

Medical College of Virginia
Graduation Year: 1965
Practice: Consultant
Employer: Practice Management Associates, Inc.

I am president of Practice Management Associates, Inc., a consulting firm specializing in managed health care. As a pharmacist, journalist and community activist, I have appeared on local and national radio and television commenting on health and education and I am also a noted local and regional newspaper columnist. I served during the Governor William Donald Schaefer administration as a member of the Maryland Board for Community Colleges where I helped govern a program with a $100 million budget and 78,000 students. I am past chairman of the board of the Harford Belair Mental Health Association, and I am past president of the Baltimore Metropolitan Pharmacists Association. I served at the invitation of Baltimore Cardinal William Keeler and Maryland Governor Schaefer on the executive committee of the Archdiocese of Baltimore's Tricentennial Benefit Concert, raising over $100,000 for Maryland's needy and I served as fund raising chairman of St. Dominick's School in Hamilton where I completed a $200,000 fund raising commitment. I was also one of the founders of the Harvest for Health, a nationwide program to collect and distribute thousands of pounds of health care products for the needy. In October 1995, I was selected as the 1995 recipient of the U.S. Pharmacist/Searle Service to the Community Award, the national award given to an individual pharmacist who has distinguished him or herself in the service of their community and their fellow citizens.

I will strive if re-elected treasurer, to continue to provide the association with a prudent approach to fiscal responsibility, and I will exhaust all possibilities in helping to raise additional funds to improve the Kelly Building.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #1

Richard D. Baylis, C.G.P.
7600 Water Oak Point Road
Pasadena, MD 21121

Albany College of Pharmacy
Graduation Year: 1961
Practice: Long Term Care
Employer: HMIS Omni Care

I ask for your support to continue my service as a Trustee of the Maryland Pharmacists Association. During my service as Trustee for the past several years, I have served as the Association's representative on the Task Force preparing the Collaborative Practice Act and Drug Administration Act. I have also been Co-Chair of the Legislative Committee, and a member of the Building Committee.

This coming year, the practice of pharmacy in Maryland faces a great challenge in persuading the state legislature to pass the Collaborative Practice and Drug Administration Acts. I am actively involved with the Board of Pharmacy in promoting this legislation. If successful, pharmacy practice in this state can move forward into the next century.

In addition to my service to the Maryland Pharmacists Association, I am a board member of the American Society of Consultant Pharmacists - PAC and the Maryland Chapter of ASCP.

Douglas Haggerty, P.D.
800 North Pine Ridge Court
Bel Air, MD 21014

University of Maryland School of Pharmacy
Graduation Year: 1979
Practice: Community Pharmacy
Employer: Target Pharmacy

I am interested in serving as a Trustee for several reasons. Pharmacy practice is currently undergoing great change, regardless of practice setting. That is why I feel it is extremely important for our Association to evolve as well. Just as I have pursued a personal evolution by enrolling in the Non-traditional Pharm-D program, I will make sure that our Association is able to evolve and continue to meet our changing needs. I also feel that our strength lies in unity, and I will work to forge alliances with other organized pharmacy groups. And lastly, I believe in *The Power of One*, that is, we each can contribute to the profession in our own way, by being involved, and I will work to make the Association a voice for every pharmacist within the State, by active involvement of members.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #2

Alisia Billington, P.D.
48 Loveton Farms Court
Sparks, MD 21152

University of Maryland School of Pharmacy
Graduation Year: 1991
Practice: Long Term Care
Employer: NeighborCare

I hope to continue serving the association as a MPhA Board Member. My background includes community, long term care, and consulting. I hope to continue to represent the interests of all pharmacists as we face the challenges of an ever changing healthcare marketplace.

Lynette R . Bradley, P.D.
208 Lastner Lane
Greenbelt, MD 20770

University of Maryland School of Pharmacy
Graduation Year: 1992
Practice: Retail Community Pharmacy
Employer: CVS Pharmacy

As a practicing pharmacist in a community setting for over five years, a past Trustee and member of various committees in the Maryland Pharmacists Association, a preceptor for students at the University of Maryland School of Pharmacy, and a doctoral student in the Pharmacy Administration program at the University of Maryland, I have had the honor to meet, converse, and exchange ideas with future and current pharmacists in the state of Maryland. Based on these encounters as well as attending and being actively involved in many national meetings of our professional pharmacy associations, I believe that I possess the knowledge and insights concerning pharmacy that will help to advance our profession as the health care system changes. I know where pharmacy has been, where it is currently, and the possible directions that we may go in the future-- both as a separate health care profession and as a partner in the health care arena. If elected, I will continue to provide these and other expressed viewpoints concerning our profession to the Board of Trustees' table. This will only serve to establish the profession of pharmacy and our Maryland Pharmacists Association in the best possible position as we enter the next millennium.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #3

Steven Disharoon, P.D.
103 Poplar Street
Hurlock, MD 21643

University of Maryland School of Pharmacy
Graduation Year: 1979
Practice: Independent
Employer: The Drug Store

I opened *The Drug Store*, located in Hurlock, Maryland on the Eastern Shore, and have been practicing pharmacy in this rural setting ever since. My reason for running for office is to stay involved as an active participant in the rapidly changing pharmacy profession.

Gary L. Haas, R.Ph.
7628 Old National Pike
Boonsboro, MD 21713

University of Nebraska School of Pharmacy
Graduation Year: 1971
Practice: Independent
Employer: Boonsboro Pharmacy Inc.

I would consider the honor, if elected to this position, as a Trustee of the Maryland Pharmacists Association, to represent the needs and desires of its members. I have started two pharmacies from the ground level, and I understand the difficulty of maintaining a profitable pharmacy at all levels of the business. I would bring these insights to these meetings as we move in the 21st century.

Statements of the Candidates

1998 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #4

Marcus T. Carson, P.D.
3827 Janbrook Road
Randallstown, MD 21133

Howard University School of Pharmacy
Graduation Year: 1970
Practice: Retail Community Pharmacy
Employer: Pharmacy Owner

As a retail pharmacist, I have been in practice for 27 years. There is a tradition of pharmacy in my family. My wife is a pharmacist and my son is currently in pharmacy school. I have a deep stake in how pharmacy is now practiced as well as how it will look in the future.

The practice of pharmacy has undergone drastic changes in the last five to ten years. Some of these have been positive and some have been negative, but all have been challenging. The next millennium holds opportunity for even more drastic changes. It is critical that pharmacists, who care about the profession, be involved to affect these changes for the benefit of our profession and the benefit of the patients we serve. If I am chosen to serve as a board member, I will utilize all of my skills and resources to benefit the Maryland Pharmacists Association and thereby our profession.

Scott Kuperman, P.D.
6314 Dry Stone Gate
Columbia, MD 21045

University of Maryland School of Pharmacy
Graduation Year: 1988
Practice: Independent
Employer: Crain Towers/EPIC Pharmacy

If elected to this position, I will strive to represent all aspects of the pharmacy profession and further the goals of the Association to the best of my ability. As a preceptor for UMAB, I see how well our students are being trained to practice pharmaceutical care. By the same token, we must not lose sight of the importance of the skills that make pharmacy distinctive. Only by augmenting both aspects can pharmacy survive in the future.

With the tremendous upheavals in health care, it is vital that pharmacists stay on the forefront of change. Pharmacy has in the past faced changes reactively, often to its detriment. It is critical that we remain proactive to ensure our future.

Pharmacy has give so much to me personally. It would be an honor if you would allow me the opportunity to give something back to the profession. Thank you for your consideration.

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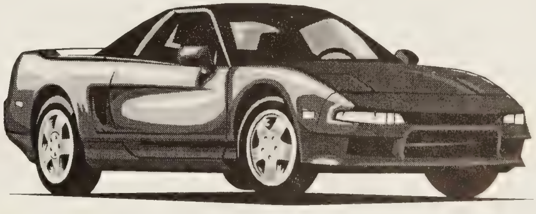

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DRUGGISTS/PHARMACISTS AGAIN TOP GALLUP POLL

In earning the CNN/*USA Today*/Gallup Poll's highest rating for honesty and ethics ever, pharmacists/druggists have been named the nation's most trusted professionals for the ninth straight time.

The 1997 CNN/*USA Today*/Gallup Poll of 26 professions shows that 69 percent of American consumers rate the "honesty and ethical standards" of pharmacists "very high" or "high." The next most trusted professionals, the clergy, were fully 10 points behind at 59 percent.

The pharmacists' numbers rose by five percentage points, marking the highest high/very high percentage accorded any profession in the 20 years that the Gallup honesty and ethics polls have been conducted. The pharmacists first topped Gallup's "most trusted professionals" poll in 1988. Last year's poll showed pharmacists at 64 percent, eight points ahead of the clergy.

"Achieving the Gallup Poll's highest rating ever is particularly rewarding," said NCPA President Ken Epley of Salem, Oregon. "The nation's independent community pharmacists are clearly doing something right. Our patients trust us. They value highly both the medicines we dispense and the counseling we provide."

The CNN/*USA Today*/Gallup Poll asked more than 1,000 adults to rate the honesty and ethical standards of 26 different occupations. Those surveyed gave ratings of very high, high, average, low, very low, and no opinion. The survey was conducted November 6-9, 1997.

Medical doctors, the next highest health care professional, ranked third with 56 percent -- 13 percentage points behind pharmacists -- while college teachers ranked fourth with 55 percent. Dentists were fifth at 54 percent.

"At a time when so much of the reporting in the media focuses on the negative, on what's wrong with our health care system," said Epley, "it's gratifying to see that, more than ever, patients respect their neighborhood pharmacist and value the personalized professional care we provide."

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January 1998 Volume 120 Number 1

1998 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

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☐ Joseph A. DeMino, P.D.

Vice-President

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When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, ***postmarked by Saturday, May 2, 1998***. For questions, please call MPhA at 800-833-7587.

Fold

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1998 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

Topiramate (Topamax^R) for the Treatment of Partial Seizures

Aatif Sheikh
4th Year Pharm.D. Student

Epilepsy is a chronic neurologic disorder which affects many Americans. This disorder affects people of all ages. However, the emergence of the first seizure normally occurs in newborns, young children, and in patients over the age of 65.[1]

Epilepsy refers to a group of disorders characterized by recurring seizures. Therefore, a person who has a seizure does not necessarily have epilepsy. Epilepsy is further classified as symptomatic, if the cause is known, or idiopathic, if the cause is unknown. The type of seizure a patient has is also classified as either partial or generalized. It is important to classify a seizure properly so that appropriate therapy may be instituted.[1]

Recently the FDA has approved a number of new medications for the treatment of seizure disorders. Topiramate is a novel oral anticonvulsant agent with multiple mechanisms of action and potent anti-seizure activity. It is used for adjunctive therapy for partial seizures with generally transient, mild to moderate side effects. It is a sulfamate-substituted derivative of the naturally occurring monosaccharide d-Fructose.[2,3,4]

The precise mechanism of action by which topiramate exerts its anti-seizure effect is unknown. However, studies have revealed 3 properties which may contribute to its anti-epileptic efficacy. Topiramate reduces the duration of epileptiform discharges and the number of action potentials generated within each discharge, probably by blocking voltage dependent sodium channels, it enhances the activity of GABA at a non-benzodiazepine site on $GABA_A$ receptors and, it antagonizes a non-N-methyl-d-aspartate(NMDA)-glutamate receptor. A fourth effect which has no bearing on topiramate's anti-epileptic activity but may be relevant for drug-drug interaction profile is its weak inhibitory effect on the isoenzymes of carbonic anhydrase. This effect is significantly weaker than that seen with the use of acetozolamide.[5,6]

In patients with normal renal function, the half-life of topiramate is approximately 21 hours. Therefore, steady-state levels are achieved in approximately four days. Topiramate exhibits rapid absorption which varies on a per individual basis from 1.8 to 4.3 hours. Food appears to have no effect on its absorption. It is excreted in the urine with 80% being unchanged and the other 20% being metabolized in the liver into six inactive metabolites.[7,8,9]

Most adverse drug reactions due to topiramate have typically been transient. Most adverse effects usually develop during the titration period of the drug. Adverse effects which had a greater incidence than with placebo include psychomotor slowing, difficulty with concentration, speech or language problems, somnolence, or fatigue. In one study, 32/3086 patients reported the occurrence of kidney stones with the use of topiramate. This is 2-4 times the incidence seen in the normal population.[10,11]

Studies using topiramate in conjunction with other anti-epileptics, oral contraceptives, and digoxin have shown drug interactions which have led to increased concentrations. However, none of these interactions were shown to be clinically significant. Use of a carbonic anhydrase inhibitor with topiramate may create a physiological environment that could increase the risk of renal stone formation and therefore should be avoided.[12,13,14,15]

In patients with renal disease it is recommended that the dose of topiramate be reduced by 50%. Currently, no studies have been done on topiramate use in children so should generally be avoided. Also, topiramate is pregnancy category C. Teratogenic effects have been shown in animals, but no studies in pregnant women are available.

In summary, topiramate is a new anti-epileptic agent several mechanisms of action for use as an adjunct for treatment of uncontrolled partial seizures. It has many benefits over traditional anti-epileptic drugs such as low-protein binding, first order pharmacokinetics, inactive metabolites, high renal excretion, rapid absorption, low drug interaction potential, linear increases in plasma concentrations following large doses, and minimal pharmacological effect on cardiovascular, gastrointestinal and endocrine systems. Topiramate provides the health care professional with another tool to combat partial seizures.

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HEALTH NOTE

Canker Sores (Aphthous Ulcers)

The Most Common Ulcerative Condition in the Mouth

They can be painful, irritating, and annoying. They can often interfere with smiling and the pleasure of eating. They are aphthous ulcers, commonly known as canker sores. Canker sores are small ulcers with a gray or white base and red border. They are the most common ulcerative condition in the mouth.

A specific cause for canker sores is unknown. A variety of factors, however, appear to be linked to their development. These include stress, hormonal changes, trauma, fatigue, bacterial infection, nutritional deficiencies, allergies and immunologic abnormalities. Self-inflicted bites or reactions from hot goods or drinks may contribute to the development of aphthous ulcers. Canker sores are not contagious.

Canker sores or Recurrent Aphthous Stomatitis (RAS) is a self-limiting condition of the oral cavity. (A self-limiting condition is one that will naturally heal over time without any treatment.) The appearance of small painful ulcers on the oral mucosa (internal lining of the mouth) characterize the disease.

Canker Sores vs. Cold Sores

Many people often confuse canker sores with the common cold sore. This mistake is easily made. The diseases share similar appearance and development and underlying causes such as stress, trauma and fatigue. There is one significant distinction. Cold sores are the result of herpes simplex, a viral infection, and are generally found on the lips or fixed linings of the mouth. Canker sores, on the other hand, are generally found on the moveable lining of the mouth such as the tongue or the lining of the cheek. An easy way to distinguish between the two is to remember that canker sores generally occur inside the mouth, and cold sores usually occur outside the mouth.

A new prescription medication is now available to dentists and physicians to provide help to the millions of canker sore sufferers in the United States. Block Drug Company announces the introduction of Aphthasol (amlexanox oral paste, 5%) - the first and only prescription medication indicated specifically for the treatment of canker sores, in patients with normal immune systems.

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Interactions....

Early Intervention Improves Care While Cutting Costs

David A. Knapp, PhD
University of Maryland School of Pharmacy

Ilene H. Zuckerman, R.Ph., Pharm.D.,
Geriatrics and Ambulatory Care,
University of Maryland; Associate
Professor, Pharmacy Practice and
Science

Through a study designed to improve both clinical and cost outcomes for Medicaid recipients, pharmacists and physicians are taking a cooperative new look at the medication prescribing process. Developed by Dr. Ilene Zuckerman, the study provides pharmaceutical staff support and evaluative assistance from the School of Pharmacy and the Center on Drugs and Public Policy to four adult general medicine clinics in Baltimore.

"We impact upon pharmaceutical care at the site of prescribing, as opposed to the site of dispensing, which is more traditional," says Dr. Zuckerman. "We put pharmacists where the prescribers make their decisions."

The clinics are affiliated with teaching hospitals, but pharmacists are not available for all clinics, which provides an ideal control for the study. For a selected clinic, a pharmacist arrives early to review patients' medical records. The pharmacist determines which patients are most likely to benefit from an intervention, a decision based largely on whether there is concern about current drug therapy or a diagnosis for a targeted disease--hypertension, diabetes, hyperlipidemia or asthma.

When the clinic opens its doors, the pharmacist conducts interviews with selected patients to collect more information regarding medication history and compliance with a regimen. Then the pharmacist compiles all the data and provides a written pharmacotherapy consult to the physician, which becomes part of the medical record. Clipped to the front of a patient's chart, the consult documents any patient education the pharmacist provided, suggests changes in drug therapy or laboratory monitoring, mentions cost-beneficial alternatives to current prescriptions, and informs the physician about national guidelines for therapeutic decision making.

Since the doctor receives this information before seeing the patient, the pharmacist can have a positive impact on medication decisions. The physicians, who are usually medical residents, also receive valuable training regarding drug therapy issues. "It's a teachable moment," says Dr. Zuckerman.

Although attending physicians in the clinics are now uniformly positive about the pharmacists' involvement, some clinic administrators needed initial reassurance that pharmacists would not be undermining physicians' decisions. In an ironic turn of events, changes in health care and Medicaid procedures necessitate that the pharmacists wrap up their work, and the clinics are searching for ways to keep them.

Why? Because study results indicate that early, prediagnostic cooperation between pharmacist and physician reaps rewards in better health care and lower costs. In her doctoral dissertation, Dr. Lian Lai measured the economic benefits of this program to the payor, Medicaid. "In the study group, as opposed to the control group," observes Dr. Zuckerman, "Dr. Lai showed that there was an increase in primary care visits--visits to general internal medicine doctors--and a decrease in visits to specialists. The opposite was true of the control group. The implication is that the pharmacists had an impact on helping clinic physicians better manage the targeted chronic diseases so patients had less need to be referred to specialists."

In determining dollar implications, Dr. Lai's study looked at total costs to the payor--doctor visits, emergency room visits, hospitalizations and drug expenses--between the study and control groups. For a fixed period from pre-intervention to post-intervention of pharmacists, total costs remained basically the same for the study group, while costs rose 13 percent for the control group. Prescription costs were broken out for each group as well, and patterns were similar. The cost of prescription drugs in both groups increased during the same period, but costs for the study group rose 20 percent less than for the control group.

When Dr. Lai determined net savings per patient through a comprehensive formula that included the cost of the program itself, the analysis showed a net savings of $200 per patient for the study group in the first year. With the switch to managed care in Medicaid, pharmaceutical care services become the responsibility of each managed-care organization. Thus, these economic benefits will favor individual managed-care organizations and not Medicaid directly.

Now the state has asked Dr. Zuckerman's team to develop quality assurance measures for pharmaceutical services for managed-care organizations, and she is ready for the opportunity. "We have the ability to impact in that way," she says confidently. "I'd like to market these services outside of Medicaid to managed-care organizations, to keep the models going. We have good data to show the cost benefit to the payor. We *can* save them money, and at the same time, improve quality of pharmaceutical care to their patients."

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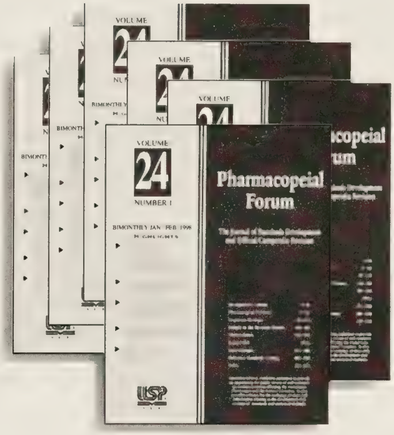

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Recognizing Pharmacy Excellence
The 1998 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 116th Annual MPhA Convention.

For consideration, all nominations must be received no later than ***April 15, 1998***.

- **Hoechst Marion Roussel Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who has graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1989 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time.
  Who is Eligible: Any long standing contributor to the profession or the Association.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during ***either*** the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions.
  Who is Eligible: Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **DuPont Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. This may include adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be complete and returned to the Maryland Pharmacists Association no later than ***April 15, 1998***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐***Hoechst Marion Roussel Distinguished Young Pharmacist Award***
Nominee ______________________________
Home Address ______________________________
City/State/Zip ______________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone ______________________________
Name of Nominator ______________________________
Nominator's Phone ______________________________

☐***Seidman Distinguished Achievement Award***
Nominee ______________________________
Home Address ______________________________
City/State/Zip ______________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone ______________________________
Name of Nominator ______________________________
Nominator's Phone ______________________________

☐***Dupont Innovative Practice Award***
Nominee ______________________________
Home Address ______________________________
City/State/Zip ______________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone ______________________________
Name of Nominator ______________________________
Nominator's Phone ______________________________

☐***Wyeth-Ayerst Bowl of Hygeia***
Nominee ______________________________
Home Address ______________________________
City/State/Zip ______________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone ______________________________
Name of Nominator ______________________________
Nominator's Phone ______________________________

☐***MPhA Honorary President***
Nominee ______________________________
Home Address ______________________________
City/State/Zip ______________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone ______________________________
Name of Nominator ______________________________
Nominator's Phone ______________________________

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street, Baltimore, MD 21201-1572

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Awards Nominations
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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Digoxin Intoxication and the Use of Digoxin-Specific Fab Antibody Fragments

Lisa Booze, BSPharm, CSPI
Clinical Coordinator
Maryland Poison Center

Digoxin is widely used in the treatment of supraventricular tachyarrhythmias and congestive heart failure. However, there is a narrow margin between therapeutic and toxic doses. In the past, the treatment of digoxin toxicity was largely supportive and aimed at inhibiting the absorption of the drug or counteracting its cardiac effects. In massive overdoses, standard supportive therapy has limited effectiveness often resulting in fatal outcomes. The need for effective treatment for severely toxic patients led to the development of digoxin-specific Fab antibody fragments.

There are many reasons why patients develop digoxin toxicity. Pediatric poisonings are usually the result of accidental ingestions, or errors in the calculation or administration of therapeutic doses. Intentional overdoses in adolescents and adults often result in acute toxicity. Patients who are taking digoxin chronically may become toxic from several disease and drug interactions (hypokalemia, hyperkalemia, hypercalcemia, hypomagnesemia, impaired renal function, and concomitant use of diuretics, glucocorticoids, quinidine, amiodarone and verapamil).

The incidence of toxicity due to digoxin is difficult to quantify due to the fact that although as many as 35% of digitalized patients are said to develop toxicity, many go unreported. In 1996, there were 2,862 cases of cardiac glycoside overdoses reported to the American Association of Poison Control Centers. Unintentional exposures were reported in 2,306 of the cases. In 97 cases, major toxic effects developed, and there were 16 documented fatalities.

Digoxin exerts its inotropic effects by inhibiting the activity of the enzyme Na^+/K^+ ATPase, resulting in a gradual accumulation of intracellular Na^+ and a loss of intracellular K^+. The increase in intracellular Na^+ causes myocardial Ca^{++} to increase resulting in an increase in the force of muscle contraction and a decrease in conduction through the AV node. Digoxin's toxic manifestations are an extension of its pharmacologic effect. Inhibition of the Na^+/K^+ pump results in an increase in extracellular K^+ and acute overdoses are characterized by hyperkalemia. Chronic intoxications are often associated with hypokalemia. Symptoms such as anorexia and vomiting are more commonly seen in acute overdoses than chronic. Central nervous system symptoms (more often seen with chronic intoxication) are lethargy, toxic psychosis, hallucinations, delirium, weakness and visual disturbances (photophobia, aberrations of color perception and blurred vision). Cardiovascular signs and symptoms are inevitable in severe intoxications and may precede non-cardiac symptoms. Conduction blocks are more likely to occur in acute overdoses (bradycardia, varying degrees of AV block) while disturbances of impulse formation are more common in chronic overdoses. Intracellular hypokalemia reduces the threshold for ectopic pacemakers leading to AV junctional tachycardia, premature ventricular contractions, ventricular tachycardia or ventricular fibrillation.

Approximately 70% of digoxin is absorbed from tablets and 80% from elixir. Peak digoxin levels occur in 2-3 hours but may be delayed in overdoses. Digoxin has a large volume of distribution: 5-8 l/kg in adults, 10 l/kg in neonates, 16 l/kg in infants. The volume of distribution may be lower in obese patients and patients with renal failure. Excretion is by renal tubular secretion with 57-80% of a dose excreted unchanged within 6-12 hours. The elimination $T_{1/2}$ of digoxin in therapeutic doses is 36-51 hours and is shortened in overdoses to as low as 15 hours. Therapeutic digoxin concentrations range from 0.5-2.0 ng/ml. In overdoses, the distribution phase may be prolonged, therefore serum digoxin levels may not be meaningful until at least 6 hours post ingestion. Acute toxicity is usually seen above 10 ng/ml. Patients have survived 48 ng/ml but deaths have been reported with levels as low as 3.5 ng/ml. In chronic intoxications, there is an overlap between toxic and nontoxic levels, with many patients developing serious symptoms at lower digoxin levels.

Antibodies to digitalis were originally developed and used experimentally in animals in the 1960's. Digoxin-specific antibodies are produced by immunizing sheep or rabbits with digoxin that has been coupled as a hapten to an immunogenic protein carrier (serum albumin). After several weeks to months, the serum rich in digoxin-specific antibodies is harvested. The IgG antibody molecule is digested with papain into 2 Fab fragments and 1 Fc fragment. The digoxin-specific Fab fragments are isolated and purified by affinity chromatography. Fab fragments distribute rapidly into tissues, occupy a large volume of distribution, and are rapidly excreted by glomerular filtration with a $T_{1/2}$ of 15-20 hours in the presence of normal renal function.

Digoxin-specific Fab antibody fragments are indicated for treatment of potentially life-threatening digitalis intoxication with severe ventricular arrhythmias, progressive bradycardia, second or third degree heart block not responsive to atropine, and/or hyperkalemia (usually >5.5 mEq/l). Fab fragments are also indicated for digoxin ingestions of >10mg in an adult, >4mg in a child or a serum level of >10 ng/ml (6-8 hours post-ingestion).

Fab fragments are commercially available as DIGIBIND^R (Glaxo Wellcome), each vial containing 38 mg which will bind approximately 0.5 mg digoxin. For chronic intoxications, 6 vials in adults and 1 vial in children are usually adequate to reverse toxicity. Twenty vials (760 mg) are recommended in adults and children who ingest an unknown amount of digoxin acutely. An equimolar dose of Fab fragments can be calculated if the total amount of digoxin ingested acutely is known:

Digoxin body load (mg) = dose ingested x 0.8 (accounts for incomplete absorption)

$$\text{Dose (\# of vials)} = \frac{\text{digoxin body load (mg)}}{\text{0.5 mg digoxin bound/vial}}$$

If the steady state of serum digoxin concentration is known, the dose of Fab fragments can be calculated using the following equations:

$$\text{Adults: Dose (\# vials)} = \frac{\text{serum digoxin conc (ng/ml) x weight (kg)}}{100}$$

Children: Dose (mg) = dose (# of vials from above) x 38 mg/vial

Recurrent toxicity is likely to occur in patients receiving less than the estimated required Fab fragment dose. Onset is usually within 3 days but may be as late as 11 days. The decision to retreat should be made on clinical observations of the patient.

Shortly after the administration of Fab fragments, the amount of free circulating digoxin decreases to near zero but there is a rapid rise in the serum concentration of the Fab-digoxin complex. Standard immunoassays for digoxin measure both free and bound digoxin, thus total serum digoxin measurements may be meaningless following Fab fragment administration. (Techniques that separate free from bound digoxin are useful but not generally available). Renal failure slows the elimination of total digoxin after Fab therapy.

Few adverse reactions to Fab fragments have been observed. Allergic reactions appear in <1% of patients. Hypokalemia from reactivation of Na^+/K^+ ATPase occurs in less than 10% of patients. Serum potassium levels should be monitored repeatedly during therapy. Congestive heart failure may be precipitated in patients who require digoxin to maintain cardiac output. Similarly, an increase in ventricular rate might be noted in patients being treated with digoxin for atrial fibrillation. Patients who require redigitalization must wait 4-7 days for the digoxin-Fab complex to be eliminated.

Call the Maryland Poison Center for all poisoning emergencies: 410-706-7701 (Baltimore Metro area), 1-800-492-2414 (Maryland only). Visit the Maryland Poison Center web site: (www.pharmacy.ab.umd.edu/~mpc/) for more information on poisonings.

Continuing Education for Pharmacists

Volume XV, No. 10

Clinical Aspects of Antihistamine Use

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Goals. The goals of this lesson are to discuss the concepts of the treatment of allergic rhinitis with antihistamines, with special emphasis given to the AM/PM protocol which alternates nonsedating and sedating antihistamines.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the AM/PM protocol for the treatment of seasonal allergic rhinitis with antihistamines;
2. differentiate between the sedating and nonsedating antihistamines as they relate to pharmacokinetics, drug interactions, toxicities and patient compliance; and
3. identify the pregnancy categories in which FDA has placed the various nonsedating antihistamines.

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Today pharmacists need to be sensitive to therapeutic, economic and legal considerations in product selection, especially with the advent of managed care and preferred product formularies. Moreover, when pharmacists develop formularies for managed care, they must be cognizant of the FDA-approved labeling relative to safety and efficacy.

Safety Considerations

Terfenadine (e.g., Seldane) has been one of the most widely prescribed nonsedating antihistamines for the treatment of symptoms associated with seasonal allergic rhinitis (SAR). It was not until five years after its introduction that serious safety concerns were raised regarding terfenadine use. An association between terfenadine and cardiac arrhythmia (torsades de pointes [TDP]) was discovered when terfenadine was administered with ketoconazole (Nizoral), an antifungal agent. Since that time, terfenadine has been found to produce rare but potentially serious drug interactions with certain antifungal agents and macrolide antibiotics, most specifically erythromycin and clarithromycin (Biaxin), as well as with other drugs which prolong the QT interval. The list of medications known to inhibit the metabolism of terfenadine is growing and now also includes some serotonin-specific reuptake inhibitors such as sertraline (Zoloft) and recently approved drugs such as the fluoroquinolone antibiotic sparfloxacin (Zagam), and the antivirals ritonavir (Norvir), saquinavir (Invirase), and indinavir (Crixivan).

The consequences of elevated serum levels of terfenadine can be quite severe. Between 1984 and 1996, FDA reported that there were 396 deaths in patients receiving terfenadine. It has 39 reports of TDP arrhythmias, 145 reports of prolonged cardiac QT interval, and 207 reports of cardiac arrest. While there is a lack of proof that the deaths were caused by terfenadine, the issue has been raised and there are several alternative antihistamines.

In January 1997, FDA decided to seek the withdrawal of terfenadine due to the potential for cardiac side effects and because it is no longer a "unique molecule." Fexofenadine (Allegra) is the metabolite that provides the therapeutic benefits of terfenadine without the associated cardiac side effects.

Astemizole (Hismanal) is a second-generation nonsedating antihistamine that is effective for relief of symptoms associated with SAR. However, it produces QT effects similar to those of terfenadine, and therefore, has the same potential for adverse cardiovascular events and adverse drug interactions when administered concomitantly with certain antifungals, macrolide antibiotics, or other drugs which prolong the QT interval. Like terfenadine, astemizole is metabolized extensively in the liver and should not be administered to patients with significant hepatic dysfunction. While it is administered once-a-day, its manufacturer states that the tablet should be taken one to two hours after a meal. This could cause compliance problems in some patients.

Cetirizine (Zyrtec) is a carboxylic acid metabolite of hydroxyzine. Because it is not metabolized by the hepatic cytochrome system, it is not involved in the previously described drug interactions and may be used safely by patients with hepatic dysfunction. However, sedation has been reported with its use. In one double-blind, placebo-controlled study, 23 percent of patients experienced sedation with a 10mg cetirizine dose. Further impairment results when cetirizine 10mg and alcohol are combined. Therefore, FDA does not classify cetirizine as a nonsedating antihistamine.

As stated earlier, fexofenadine is a metabolite of terfenadine. It was cleared for marketing by FDA in mid 1996. Early research indicates that fexofenadine is nonsedating and both safe and effective at the recommended dose of 60mg b.i.d. No serious cardiovascular side effects have been reported since its introduction in the U.S.

Loratadine (Claritin) is a second generation, once daily, nonsedating antihistamine which has been on the global market since 1988 and available in the U.S. since 1993. Extensive studies have shown that loratadine does not cause adverse cardiac effects and is not involved in the drug interactions associated with astemizole and terfenadine.

Considerations in Antihistamine Selection

Nonsedating antihistamines, like any medication, should be chosen to cover the broadest range of symptoms. Fexofenadine is indicated for use in patients with SAR, whereas loratadine and astemizole are indicated for both SAR and idiopathic chronic urticaria. Cetirizine is indicated for perennial allergic rhinitis (PAR), in addition to SAR and idiopathic chronic urticaria.

Studies indicate that between 80 and 91 percent of patients with SAR also suffer from congestion. Physicians treating these patients commonly prescribe a decongestant in addition to an antihistamine, either separately or a combination. Claritin-D 12 Hour and Seldane-D are examples of 12-hour nonsedating antihistamine/decongestant combinations. To maximize patient compliance, Claritin-D 24 Hour, containing loratadine and pseudoephedrine, was formulated as a once-a-day dosage form.

Some confusion resulted with both prescribers and pharmacists when Claritin-D 24 Hour was first introduced to the marketplace. Quite simply, if the dosage regimen is one tablet daily, this is the appropriate regimen for Claritin-D 24 Hour. When the dosage regimen is one tablet twice-a-day, this is the appropriate regimen for Claritin-D 12 Hour.

Given the number of younger patients being diagnosed with SAR, it is also important for antihistamines to offer safe, effective, patient-friendly pediatric therapy. Commonly, children with SAR have learning impairment. Antihistamines which cause drowsiness, such as diphenhydramine, exacerbate learning impairment.

Table 1
Drug Usage Categories During Pregnancy

Pregnancy Category A: Adequate and well controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy and there is no evidence of risk in later trimesters. If the drug is used during pregnancy, the risk of harm to the fetus appears remote. Because studies cannot rule out the possibility of harm, however, [the drug] should be used only if clearly needed.

Pregnancy Category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well controlled studies in pregnant women. The labeling should indicate that studies have been performed in specific animals at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus.

Pregnancy Category C: Animal studies have shown an adverse effect on the fetus. There are no adequate and well controlled studies in humans and the benefit from the use of the drug in pregnant women may be acceptable despite its potential risks.

Pregnancy Category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. However, the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (i.e., life threatening).

Pregnancy Category X: Animal and human studies have demonstrated fetal abnormalities or positive fetal risk based on adverse reaction reports from investigational or marketing experience.

Fexofenadine is indicated for

patients 12 years of age and older, and is available in capsule form only. Astemizole is indicated for patients as young as six-years-old, but there is no liquid form. One recommended dosage requires splitting a 10mg tablet, which may negatively affect compliance and result in less accurate dosing. Cetirizine and loratadine are also indicated for patients as young as six-years-old, and have the advantage of a syrup formulation. The sedative effect of cetirizine, however, could limit its use in the pediatric population. Loratadine is also available in a form that dissolves rapidly on the tongue (Claritin Reditabs), which simplifies dosing and may enhance compliance.

In addition to being influenced by the kind of doses that must be taken, patient compliance is also affected by the frequency of dosing. A 1990 study showed a striking rise in compliance as dosing frequency declined. Once-a-day dosing is preferred because it is more convenient, especially for parents medicating younger children. Fexofenadine is indicated for b.i.d. dosing; cetirizine, astemizole, loratadine, and loratadine/pseudoephedrine (Claritin-D 24 Hour) are indicated for once-a-day dosing.

Choices During Pregnancy

The use of antihistamines in women of childbearing age is also a concern. While all drugs should be used only with a great deal of caution during pregnancy, the safest drugs for both the mother and developing fetus are those with the highest FDA pregnancy rating (i.e., "A").

FDA has promulgated guidelines for drug usage during pregnancy which are categorized as A, B, C, D, and X, which are defined in Table 1.

Cetirizine and loratadine have been placed in Pregnancy Category B, while astemizole, terfenadine, and fexofenadine have been assigned to Category C. Again, the fact that cetirizine causes a higher level of sedation than loratadine must be considered. The fact that terfenadine affects the cytochrome P450 oxidative enzyme system would rule out its use during pregnancy.

AM/PM Protocol for Antihistamines

A dosing protocol has emerged recently which encourages twice-a-day dosing. The so-called "AM/PM protocol," which has been used in some managed care settings, is designed to reduce healthcare costs by limiting the use of a more expensive nonsedating antihistamine to the morning, followed by a less expensive sedating antihistamine at night.

It is difficult to justify clinically alternating two different antihistamines when treating SAR or any other approved indication. The arguments for it are based on the cost of therapy rather than efficacy, compliance, patient safety or kinetics/pharmacology.

Opponents to this protocol contend that the efficacy of combining sedating and nonsedating antihistamines has not been proven and is not approved by FDA, which rarely recommends combination therapy with different drugs for the same indication. There are a few exceptions to this such as antihypertensive drugs with different pharmacologic activity (i.e., thiazides with beta-adrenergic blockers, ACE inhibitors, vasodilators, etc., and the newer concept of calcium channel blockers with ACE inhibitors), and analgesics with different pharmacologic activity (i.e., aspirin or acetaminophen with a narcotic).

Combinations of different drugs that have been used for decades such as antihistamines with decongestants and ophthalmic corticosteroids with antibiotics are allowed to remain on the market even though they do not fully meet FDA's criteria for combination drugs. This is because they have been used for so long that physicians have faith in their efficacy. However, they are specifically exempted from the DESI (Drug Efficacy Study Implementation) standards.

DESI refers to a massive study undertaken by FDA in the 1970s to assure the efficacy of every prescription drug (and combination of prescription drugs) on the American market. The combination drugs available before DESI came into effect were overwhelmingly banned from the market. In order to be marketed as a fixed combination, all components of drugs approved since then must be studied together to prove they are safe and that they contribute to the combination's efficacy. Two examples of combination products used to treat peptic ulcer disease include bismuth and metronidazole with tetracycline, and omeprazole with clarithromycin.

Except for one combination of antihistamines on which FDA has not taken action, all prescription antihistamine combinations (other than with decongestants as explained earlier) have been removed from the market. None have been approved since passage of the Harris Kefauver Amendment to the Pure Food, Drug and Cosmetic Act that initiated DESI.

On the OTC market, combination products containing different antihistamines (e.g., the original Triaminic formulation) have been banned by FDA. Combination products containing different decongestants (e.g., the original Dimetapp formulation) were banned as well. FDA's opinion (recommended by its expert advisory panels that studied combination products) was that mixing different drugs with the same pharmacologic action has no proven benefit and subjects the patient to the potential for greater adverse effects from multiple chemicals. The opinion continues that the best antihistamine in the correct therapeutic strength and dosage regimen should be determined.

Opponents of the AM/PM protocol state that, given FDA's opinion, taking two different antihistamines is not in the best interest of the patient, especially when one considers the kinetics of some antihistamines.

For example, terfenadine and fexofenadine require dosing every 12 hours to achieve maximum efficacy. It has been reported that the plasma level of fexofenadine from a single dose is 27 percent lower than the plasma level from steady-state dosing (209mg/mL versus 286mg/mL respectively). Replacing the PM dose with a sedating antihistamine such as diphenhydramine might compromise the pharmacokinetic properties and, therefore, the therapeutic effect of fexofenadine, since its plasma levels would be lowest in the morning and would take time to build back up after the AM dose is taken.

Taking the circadian rhythm of SAR into account argues further against the AM/PM protocol. The sneezing of allergic rhinitis is most intense in the morning. This is due most specifically to local inflammation and reduced cortisol production during the night resulting from the body's reaction to allergens the individual came into contact with during the day.

For this reason, many experts claim that antihistamine administration regimens should be tuned in closely with chronotherapy. This means that longer acting dosage forms can be given in the morning and maintain the patient for 24 hours, while twice daily dosage forms should be administered in the morning and at bedtime. They argue that using the AM/PM protocol and administering the twice daily dosage form in the morning with a short acting sedating antihistamine at bedtime renders the patient with the least amount of therapy at the time he needs it most – in the morning.

The AM/PM protocol may cause problems with the computerized components of the pharmacy's management system. Two precepts of the OBRA '90 requirement for prospective drug utilization review are that the pharmacist must check for drug over- and under-dosing, as well as therapeutic duplication.

With the AM/PM protocol, under-dosing warnings should alert the dispensing pharmacist that neither the twice daily nonsedating nor the every six to eight hour sedating antihistamines are being prescribed in the correct therapeutic dose. Additionally, the therapeutic duplication warning should alert the dispensing pharmacist since two different members of the same pharmacologic group are being prescribed. Even though the physician intended (or is required by the insurance company) to prescribe two different antihistamines, the precepts of DUR do not account for either under-dosing or therapeutic duplication.

Most pharmacy systems record pharmacists' overriding of these warnings and log them for posterity. Whether this will require additional time for pharmacists to record why they overrode the warning or face problems later is a matter of conjecture.

Although it may be beneficial to use an antihistamine that causes drowsiness at bedtime, there is a potential that residual drowsiness may occur the next morning. This sedative hangover can cause the patient to feel drowsy and less alert in the morning which contradicts the reason for selecting a non-sedating antihistamine for that patient in the first place.

Therapeutic Considerations

Among considerations before initiating the AM/PM protocol is, *Does the antihistamine cause troublesome drowsiness?* Cetirizine and the first generation antihistamines (chlorpheniramine, diphenhydramine, etc.) cause drowsiness; astemizole, fexofenadine, loratadine and terfenadine do not cause significant drowsiness.

Is the antihistamine implicated in potentially dangerous, sometimes contraindicated drug interactions? Astemizole and terfenadine interact with other drugs that affect the cytochrome P450 enzyme system and are contraindicated for concurrent therapy with many azole antifungals, macrolide antibiotics and serotonin specific reuptake inhibitors. Cetirizine, fexofenadine and loratadine are not implicated in these interactions.

How safe is the use of the drug in women of childbearing age? Astemizole, fexofenadine and terfenadine are classified by FDA as Pregnancy Category C. Cetirizine and loratadine are classified as Pregnancy Category B. By definition, Category B drugs are safer for use in women who are pregnant or may become pregnant while taking the drug.

Does the dosage regimen increase compliance? As mentioned earlier, there is a striking rise in compliance as dosing frequency declines. The dosage regimen for fexofenadine and terfenadine is one tablet or capsule twice daily (for diphenhydramine and the other first generation antihistamines, multiple daily dosages are needed). The dosage regimen for astemizole, certirizine and loratadine is one tablet once a day.

A consideration which is of increasing concern to patients, health care practitioners, the courts, and legislatures is, *What is best for the patient?* In the quest for "cost containment," some third party payers have allegedly lost sight of this concept. Therapeutic decisions should be based on proven safety and efficacy, not how much the insurance company has contracted to pay for the drugs being prescribed.

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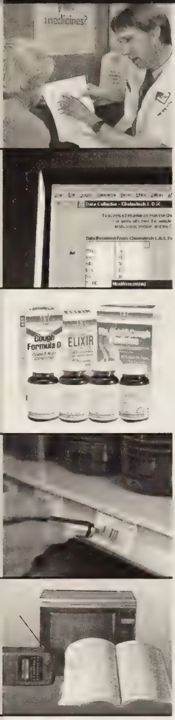

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1. All of the following are classified as nonsedating antihistamines EXCEPT:
   a. astemizole.
   b. cetirizine.
   c. fexofenadine.
   d. loratadine.

2. Which of the following has been implicated in potentially dangerous drug interactions involving the cytochrome P450 enzyme system?
   a. Cetirizine
   b. Diphenhydramine
   c. Loratadine
   d. Terfenadine

3. Which of the following combinations has been banned from the OTC market by FDA?
   a. Two different antihistamines
   b. Antihistamines with decongestants
   c. Decongestants with expectorants
   d. Analgesics with antihistamines

4. Fexofenadine has been assigned to which of the following FDA pregnancy categories?
   a. Category A
   b. Category B
   c. Category C
   d. Category D

5. The AM/PM protocol for antihistamine use refers to which of the following dosage regimens?
   a. Sedating antihistamine in the morning, nonsedating antihistamine in the evening
   b. Sedating antihistamine in the morning, decongestant in the evening
   c. Nonsedating antihistamine in the morning, sedating antihistamine in the evening
   d. Nonsedating antihistamine in the morning, decongestant in the evening

6. The exacerbation of learning impairment has been demonstrated with which of the following antihistamines?
   a. Fexofenadine
   b. Astemizole
   c. Loratadine
   d. Diphenhydramine

7. Loratadine has been assigned to which of the following FDA pregnancy categories?
   a. Category A
   b. Category B
   c. Category C
   d. Category D

8. The dosing regimen for Claritin-D 24 Hour is:
   a. one tablet once a day.
   b. one tablet twice a day.
   c. one tablet three times a day.
   d. one tablet four times a day.

9. Which of the following antihistamines is most likely to produce a morning "hangover" effect?
   a. Fexofenadine
   b. Astemizole
   c. Loratadine
   d. Diphenhydramine

10. Because of the body's circadian rhythm, the sneezing of allergic rhinitis is more intense:
   a. in the morning.
   b. in the evening.

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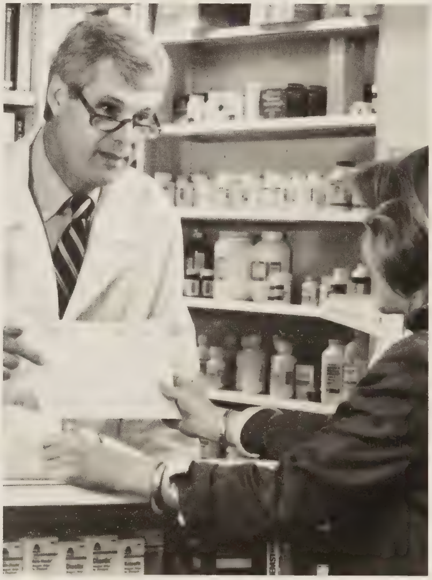

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4/98

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Maryland Pharmacist

The Official Publication of the Maryland Pharmacists Association

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Presidents Commentary

Your Profession - Your Future

As I pointed out in my previous commentary, pharmacists often don't promote themselves effectively to the public as part of the healthcare team. Therefore, I applaud the Board of Pharmacy for conducting a media campaign that, in part, will promote the role of pharmacists. I hope this campaign will highlight pharmacists as *drug information specialists*. This exposure, free from commercialism, will be an important "first" for our profession. You often read or hear that "pharmacists are the most trusted professionals," but does the public truly know all that we do? Maybe because the public trusts us, they don't bother asking about the specifics of our profession.

I feel, the fact that the Board of Pharmacy recognizes this quandary and has sought a possible solution shows tremendous insight on their part. Hopefully, all the major pharmacy groups in Maryland (MPhA, Board of Pharmacy, MSHP, and the School of Pharmacy) will continue to aspire to collaboratively promote the profession of pharmacy. The Board of Pharmacy's duty is twofold, to regulate the profession and to protect the public safety. To fulfill this mission, the Board of Pharmacy has drafted a "Pharmacists Code of Conduct" which will be promulgated as regulation after a comment period by interested parties. (It appears in the April issue of the Board's bulletin). I urge every pharmacist to read, question the areas which are a concern to you, and comment on this Code of Conduct. After all, ***it's your profession, and your future***. Don't assume that your comments won't make a difference.

After reviewing the proposed regulation, I am inclined to question certain sections. Specifically, section number 13–Reporting Others– "A pharmacist shall report conduct which departs from the standard of care ordinarily exercised by a pharmacist, and conduct pertaining to the practice of pharmacy likely to deceive, defraud, or harm the public." I feel this portion of the code could potentially create multitude of problems because of its vagueness. Would deceptive advertising fall into this category? Isn't "conduct which departs from the standard of care ordinarily exercised by a pharmacist" a huge gray area? Wouldn't the reporting pharmacist be more likely to incur some legal action (such as a slander lawsuit) because this area is not clear? These questions, and others, should be addressed. Although I have concerns regarding various aspects of the proposed regulation, the concept of a Code of Conduct is both critically important and well overdue.

Directors Column

The New Convention and Mid-Year

Robert J. Boerner
Executive Director

The MPhA Convention Committee has worked very hard this year to redesign the Mid-Year Meeting and the Convention. The Mid-Year was given more of a business focus and the Convention will have a more social atmosphere. The goal in both cases is to retain the essential character and appeal of these meetings while blending innovation into some of the scheduling and programming. If this new philosophy takes hold, in the future you will be able to come to the Mid-Year for CE and talk to the exhibitors, and you will be able to come to the Convention in June for CE and to enjoy meals, social events and the beach with your family.

The 1998 the Mid-Year Meeting was expanded to a two-day format Saturday, February 28 and Sunday, March 1. The Sheraton Baltimore North in Towson was the site of this year's Mid-Year because of its more convenient location and because the Loews Hotel in Annapolis was no longer large enough for us. The most important change was that the Exhibition was added, but the traditional CE on new drugs were retained. The other change was that the House of Delegates incorporated a new Town Hall/Open Discussion session. Those who attended liked the new format for the meeting and the House of Delegates and gave them high marks on their evaluations. The Committee is considering retaining both formats in the future.

The 1998 Convention will be held from Saturday, June 13 to Tuesday, June 16 in Ocean City at the Sheraton Fontainebleau is also undergoing some changes while maintaining tradition. The city and the hotel remain the same, but the meeting this year has been moved from Father's Day Weekend to the previous weekend and will take place Saturday through Tuesday instead of Sunday through Wednesday.

The Convention Committee has planned that, like last year, dual track CE will be offered so you can pick and choose your CE and get tracks and ample credits. The meals and other events will be generally less formal to encourage more family participation. Some CE topics are in a mental health track - dementia, psychosis, depression, bipolar disorder, anxiety, anticonvulsants, aggression and ADHD. Some topics address technical subjects - the internet and technology 101 and others vary like compounding, diabetes and ethics. The two most unusual are on weapons of mass destruction and stress. The latter is titled, *"How to Catch Your Breath When You're losing your Mind."*

In place of the Exhibit, the Committee has planned an Educational Showcase for Saturday night. The Showcase will allow a select group of companies to exhibit and provide mini CE's or demonstrations of their new or foremost products. You can visit the exhibitors, choose those that interest you, watch a presentation, a video or a demonstration and possibly get CE credit.

There are some new ideas for the meal and social functions of the Convention. Dessert will be served Saturday night during the Educational Showcase and a magician will be there to entertain the kids while you are busy. The awards banquet will take place as in previous years, however, the crab feast will be held at Phillips Crab House and will provide good food and good fun for all.

Of course, the Committee hopes each of you who reads this article or receives registration materials will decide that their hard work was worthwhile and that you will attend the Convention to get some great CE, enjoy the beach and see the changes for yourself. Hope to see you there!

It's Time to Share Our Successes

Robert E. Smith, Pharm.D., Professor of Clinical Pharmacy Practice
Bruce A. Berger, Ph.D., Professor of Pharmacy Care Systems, Auburn University

Recently, a community pharmacist in Nebraska discussed his pharmaceutical care practice. He described his innovative approaches for providing pharmaceutical care services to his patients including, a hypertension program, a hyperlipidemia program, a lifestyle modification and weight control program, an asthma program and a diabetes program. He also mentioned his net profit for this past year had increased substantially since he had provided his patients with disease management care. This pharmacist commented that he had approached one of the competing pharmacists in his community about providing some of these same services. The colleague told him that these services were not within the realm of pharmacy practice and he would not be providing them. Whether or not the second pharmacist accepted the invitation to expand his practice into disease state management is not important for this discussion. However, what is important and what was most impressive was this pharmacist's willingness to share his success with his colleague, and perhaps even more so, his offer to assist this pharmacist in developing these same services for his patients.

As a result of this example and through mutual discussion, we have given a great deal of thought to the need to develop a greater sense of interdependence among pharmacists and to change what may be the prevailing attitude that we are all competing for a scarce piece of a very small pie. Perhaps the pie seems small now, but to make it larger, an attitude of interdependence must prevail among pharmacists.

More recently, at a program on developing the pharmacist's role in disease state management, an individual who was currently billing patients was asked if she might share her experiences with the other 150 pharmacists in the auditorium. She said no. Her attitude was the opposite of what we are advocating. However, we recognize that a competitive attitude does prevail among many pharmacists. Yet, we believe that our collective future existence depends upon all pharmacists having an interdependent attitude about sharing their professional practice experiences. We must discuss our professional and economic successes with each other if we ever hope to advance the practice of pharmacy beyond the simple acts of dispensing and counseling patients.

The basic premise for community pharmacy interdependence is that our collective success is dependent upon sharing our individual successes. If we desire health care payers to more fully compensate us for our services, then the standard of practice must progress to the point where most of us are submitting documentation for compensation for the patient care services we actually provide. The only way for this to happen is for us to share with each other what we are doing and help instill the courage within others to change their practices. The pharmacist pioneers of these innovative health care services must discuss with other pharmacists, even with the pharmacists in their own communities, what services they are providing, how they are documenting these services, how they are billing for these services, what percentage of their compensation claims are being paid, and how their patients are accepting these new services. If we keep our successes to ourselves, then the rest of the profession is unaware of possible innovative ways to advance and we are unable to take advantage of the window of opportunity before us.

You say, why should we tell our competition what we are doing? Will they not emulate our success and decrease our chances of maintaining the net profit margin we have worked so hard to attain? The answer is simple. There are enough patients and dollars for all of us. For example, there are roughly 60,000,000 hypertensive patients in the United States. Sixty percent of these patients are overweight and over half of all hypertensive patients do not know they have the disease. Assuming approximately 40,000,000 patients would benefit from a pharmacist's lifestyle and weight reduction program as well as a hypertension program and that there are close to 50,000 community pharmacies in the United States, then the pharmacists in each pharmacy could provide disease management services for approximately 800 overweight hypertensive patients. If each of these patients provided for an additional $500 annually in compensated services, each pharmacy would gross an additional $400,000 annually. This would be enough extra income for all of us. However, we may not get this additional income, if we do not share our successes and collectively raise the standard of pharmacy practice. Similar figures can be developed for disease such as diabetes, asthma and hyperlipidemia.

Let's use the airline industry as an example of interdependence. The airline industry is very competitive, yet they share a common reservation system, and for the most part, they will honor each others' tickets in the event a flight is canceled or overbooked as is often the case. All of the airlines benefit by agreeing collectively to provide these services for each others' passengers. Together they raise the service standard of the airline industry so that more people will fly and every airline wins. In Pharmacy, every pharmacist will win if we improve the profession collectively. If we hide our individual successes, then the collective forward progress of the pharmacy profession will be slower.

So, now that you are "convinced" that you should share your successes with your pharmacist colleagues, how should you do that? One way would be to write up your successes and send your short innovative practice reports to the association for possible publication in the "*Maryland Pharmacist*." Also, when you attend a state or national pharmacy meeting, speak out about your successes and failures. Other pharmacists can learn from both.

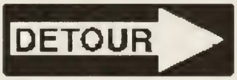
In addition, if you are not providing disease state management services, begin to do so now. Even if it is only one patient, that is a beginning. Think about this. There are 150,000 practicing pharmacists in the U.S. If only one-third of those pharmacists submitted documentation for compensation for services rendered to a patient with a chronic illness, the profession *collectively* would provide third parties with 60,000 pieces of evidence that this is not an isolated way of practicing. Our standard would be raised and the profession would be in a much better position to negotiate compensation for cognitive services. Initially, would every one get paid? Probably not. Would someone? They already are. A collective, proactive submission of well-documented claim forms will have a tremendous impact on those providing the funding for health care in Maryland. And, it would initially require focusing intensively on one patient per month.

Simply put, our collective future will be stronger if we share our successes. Those of you who are having success, please tell others how you are doing it. Your success will give another pharmacist the confidence and vision to move forward with their practice. Let's not hide our light under a basket. Let's share it and move the profession of pharmacy forward as rapidly as possible.

This article is reprinted with permission from the November 1997 issue of "Alabama Pharmacy."

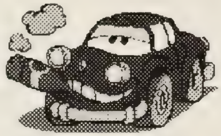
**MPHA
116TH ANNUAL
CONVENTION
AHEAD**

**JUNE 13-16, 1998
OCEAN CITY,
MARYLAND**



**TURN TO PAGE 9
AND THEN
FOLLOW THE
SIGNS TO
OCEAN CITY**

Auto Tips: Summer Car Care



It's summer time, and many car owners are not only relaxing and soaking up the sun, but they're also communing with their cars, washing and waxing on a sunny afternoon.

The following tips and information will help keep you and your car cool this summer.

Overheating
A common problem during the summer months is overheating. Don't panic! Overheating is a common problem in cars, especially older vehicles, and there are several suggestions on how to avoid and treat an overheated car.

To Avoid Overheating

- Check hoses for cracks and sponginess
- Check to see that connections are tight and leak-free
- Inspect the fan belt for cracks and proper tension
- Check the fluid level and radiator for leaks
- Check the thermostat for proper operation
- Check the radiator grill for obstructions

If Your Car Overheats

- Don't turn off the engine
- Shift to neutral and race the engine moderately for 30 seconds at two-minute intervals
- Shut off the air conditioning
- Finally, turn on the heater for a few minutes--that increases coolant flow

How to Protect Your Car From Thieves
Summer time finds more consumers vacationing and relaxing. Unfortunately, car thieves don't take a vacation. While you're on vacation, out on the town, or visiting friends this summer, protect yourself from being a car-theft victim.

Anti-Theft Basics

- Remember, a quality security device installed on your car may cost a lot, but it pays for itself many times over. Your insurance company may even offer excellent premiums for a car with an anti-theft system.
- A little red light under the dashboard and a sticker advertising your alarm system are excellent deterrents.
- When you park against a curb, turn the wheels sharply to the right with the front of the car pointed inwards as to deter theft by towing. Towing can also be deterred with a car alarm that sounds when a car is tilted.
- Have all the windows and major parts etched with the car's Vehicle Identification Number (VIN); thieves know body shops subject to police search will not accept these parts.

Summer - A Hot Time for a Cool New Car
Maybe its the weather that convinces you it is time to get the convertible you've always dreamed of. Or maybe the summer has found you in need of a bigger car or mini-van to accommodate a new little member of the family. Whatever your situation, the summer is a great time to purchase a new car or truck.

Auto Tips was provided by the Motor Vehicle Certification Program (MVCP), a free consumer protection service for those in the market for a new car or truck. MVCP's consumer advisors are automotive experts, available to help you get a great deal with no hassle.

A no-charge *member benefit* provided by the Maryland Pharmacists Association, MVCP has a network of participating dealerships that offer cars and trucks at reduced pricing. Names of participating dealerships and up-to-the-minute pricing and rebate information are just a phone call away. Call 1-800-345-0990.

Auto Tips provided by the Motor Vehicle Certification Program

The 116th Annual MPhA Convention

Join us for MPhA's 116th Annual Convention. We have planned a challenging series of continuing education programs focusing on the issues facing pharmacists. In addition, you're sure to enjoy the evening social events – a chance to meet old friends, new friends, or spend time with your family. We have provided all this and more at Maryland's premiere resort – Sheraton Fontainebleau Hotel, Ocean City, Maryland. Stay for one day, the weekend, or the entire time. Come for the fun, sun and continuing education.

MPhA convention attendees can earn up to 20 contact hours toward their licensure renewal requirement. The weekend will offer a special eight hour track on mental health issues. New this year is the Educational Showcase on Saturday, June 13 during the Dessert Reception. Representatives from industry will be available to share educational information in small group settings. This event replaces the Trade Show. The business meetings have been scheduled to give everyone a chance to participate in the Association's policy decisions.

ADVANCE REGISTRATION

Please complete the registration form included in this brochure. Type or print clearly and return the form with your check or credit card information to: **MPhA Annual Convention, 650 W. Lombard Street, Baltimore, MD 21201-1572.** *No registrations will be accepted over the telephone.* If you are paying with a credit card, you may FAX your registration to the MPhA at 410-727-2253. Register before the deadline and save the $25 on-site fee. ***The deadline for Advance Registration is Monday, June 1, 1998.***

Registration opens Saturday, June 13 at 12:00 p.m. Admission to functions will be by ticket or badge only. If you have any questions about the program, call the MPhA office at 410-727-0746 or toll-free in Maryland at 800-833-7587.

ON-SITE REGISTRATION

Registration forms received after the advance registration deadline will not be processed. You will need to register on-site and add the $25 on-site fee. For child or student registrations, no on-site fee applies.

REGISTRATION FEES

Full pharmacist registration fee includes continental breakfasts, admission to all educational sessions, beverage breaks, lunches and all evening events. ***Full spouse/guest registration*** fee includes continental breakfasts, and all evening events.

REGISTRATION FEES (continued)

Daily registration fee includes continental breakfast, admission to all educational sessions, beverage break, and lunch for that day. Daily registration for Saturday also includes admission to the Dessert Reception and Educational Showcase. ***Child registration*** fee includes continental breakfasts, Saturday evening's Dessert Reception with magician. *(Fee does not include lunches, the Crab Feast and Awards Reception/Banquet.)* ***Student registration*** fee includes continental breakfasts, admission to all educational sessions, and Saturday evening's events. *(Fee does not include lunches, the Crab Feast and Awards Reception/Banquet.)* ***All evening events are by ticket only.*** *(Extra Event Tickets may be purchased separately.)*

CANCELLATION POLICY

To cancel your registration and receive a refund, a written request must be received by June 1, 1998. Cancellation requests received by this date will be processed and a refund will be issued less a $25 processing fee. Please allov 4-6 weeks for processing. All requests received after June 1 1998 will require a 100% forfeiture of monies paid.

HOTEL ACCOMMODATIONS

Maryland Pharmacists Association has been able to obtain discounted hotel rates for attendees at the Sheraton Fontainebleau Hotel. To reserve your room, call the Sheraton directly at 1-800-638-2100. You must tell the Reservation Agent you are with the Maryland Pharmacists Association to receive the special rate. A deposit equal to one night's stay is required to hold each individual's reservation. ***The deadline is Thursday, May 14, 1998.***

HOTEL CANCELLATION/EARLY CHECK-OUT FEE

Reservation cancellations must be made 72 hours prior to scheduled arrival to avoid a full room rate ("no show") charge. Should you cancel, you must have a cancellation number to receive a refund. If you stay more than one night and change your length of stay, you must notify the hotel at or before check-in to avoid an early check-out fee of $125.

ROOM RATES (per night)

Single/Double	$139
Triple	$154
Executive King	$159
Quad	$169
Studio King	$169
Cabana Suites	$275

CONDO-2 BEDROOM (per week)

Without Maid Service	$1,150
With Maid Service	$1,350

SATURDAY, JUNE 13

12:00 - 5:00
- *Registration*
  Location: Terrace Lobby Sheraton Fontainebleau Hotel

1:00 - 2:50
- *Continuing Education ~ Technology 101*
  This highly interactive practical session will focus on the basic skills needed to fit the power of technology into your practice. This session is designed for individuals with experience ranging from very little computer knowledge to power users.
  Presenter: Bill G. Felkey, MS, Auburn University
  Sponsored by: ***Glaxo Wellcome, Inc.***
  Location: Conference 1, 2, 3

2:50 - 3:00
- *Beverage Break*
  Location: Terrace Lobby

3:00 - 4:00
- *Continuing Education ~ Dementia*
  This presentation will describe the different types of dementia with a focus on the use of the acetylcholinesterase inhibitors in the management of Alzheimer's disease. Pharmacists will be able to describe the advantages and disadvantages of currently marketed and investigational drugs along with the appropriate monitoring parameters. Mechanism of action, side effects, dosing and drug interactions will also be presented.
  Presenter: Robert Michocki, Pharm.D., University of Maryland
  Location: Conference 1, 2, 3

3:00 - 5:00
- *Continuing Education ~ Meeting Unique Patient Needs through Compounding*
  Attendees will receive up-to-date information on compounding to include new and contemporary dosage forms and devices used to meet individual patient needs.
  Presenter: Artie Matthys, R.Ph.
  Sponsored By: ***PCCA***
  Location: Crystal Ballroom Hall 1

4:00 - 5:00
- *Continuing Education ~ Psychosis*
  Recent advances in the treatment of schizophrenia will be discussed. Dr. Love will focus on some of the differences between the atypical and older antipsychotic drugs as well as new outcomes data regarding these drugs.
  Presenter: Raymond C. Love, Pharm.D., University of Maryland
  Sponsored by: ***Zeneca Pharmaceuticals***
  Location: Conference 1, 2, 3

7:00 - 10:00
- *Dessert Reception and Educational Showcase*
  This reception offers something for everyone: the opportunity to satisfy your sweet tooth, meet with old or new friends, some continuing education for pharmacists, a chance to win prizes and entertainment for the children. Representatives from industry will be available to share educational information in small group settings. Please note: this replaces the Trade Show. Admission by ticket only.
  Location: Salon A & B

The Maryland Pharmacy Continuing Education Coordinating Council is approved by the American Council of Pharmaceutical Education as a provider of continuing pharmaceutical education for pharmacists.

ACPE

SUNDAY, JUNE 14

7:00 - 5:00
- *Registration*
  Location: Terrace Lobby

7:00 - 9:00
- *Breakfast*
  Location: Terrace Lobby

8:00 - 9:00
- *Continuing Education ~ Depression*
  This presentation will review the newer antidepressant agents, their side effects and drug interactions. Dr. Love will also focus on counseling of the patient receiving antidepressant drugs.
  Presenter: Raymond C. Love, Pharm.D., University of Maryland
  Location: Grand Ballroom, Salon B

8:00 - 9:50
- *Continuing Education ~ Internet 101*
  This is not just another internet session. Come hear a "surfer" expert share his secrets in making the World Wide Web easy to use. Whether you are a beginner or another "surfer," come hear about sites of special interest to pharmacists.
  Presenter: Bill G. Felkey, MS, Auburn University
  Location: Conference 1, 2, 3

9:00 - 9:50
- *Continuing Education ~ Anticonvulsants*
  This session will review the international classification of seizure disorders and the use of anticonvulsant medications. New agents such as gabapentin, felbamate, lamotrogine, topiramate and tiagabine will be discussed and their place in therapy. Also discussed will be teratogenicity, side effects and laboratory monitoring.
  Presenter: Judy L. Curtis, Pharm.D., University of Maryland
  Location: Grand Ballroom, Salon B

9:50 - 10:00
- *Beverage Break*
  Location: Terrace Lobby

10:00 - 11:00
- *Continuing Education ~ Bipolar Disorder*
  Pharmacists will learn to recognize the signs and symptoms of bipolar disorder and will review treatment with mood stabilizing drugs. Side effects and drug interactions will also be reviewed.
  Presenter: Mary Borovicka, Pharm.D., University of Maryland
  Location: Grand Ballroom, Salon B

11:00 - 12:00
- *Continuing Education ~ Anxiety*
  The pharmacist can have a pivotal role in identifying pathological anxiety and making therapeutic recommendations. This continuing education program will teach the participant to differentiate between primary and secondary anxiety, as well as to review the diagnostic criteria and treatment of various anxiety disorders.
  Presenter: Bethany DiPaula, Pharm.D., University of Maryland
  Location: Grand Ballroom, Salon B

10:00 - 12:00
- *Continuing Education ~ Weapons of Mass Destruction: Preparing Maryland Pharmacists for Biological & Chemical Terrorism*
  This session will focus on antidotes, antitoxins, antivirals and antibiotics that may need to be called upon in the event of a weapons of mass destruction release, whether it is chemical or biological in origin.
  Presenter: Richard L. Alcorta, M.D., FACEP, Maryland Institute for Emergency Medical Services Systems
  Location: Conference 1, 2, 3

12:00 - 2:00
- *Lunch - House of Delegates*
  The first session of the Association's democratic governing body will be devoted to reports from MPhA's President, Treasurer, and Executive Director and open discussion. Nominees will be sought for the positions of House Speaker and Vice-Speaker.
  Location: Crystal Ballroom Hall 1

2:00 - 3:00 • *Continuing Education ~ Aggression*
Pharmacists will learn about the many causes of aggression, including environmental precipitants, drug induced violence and psychiatric disorders that may result in aggressive acts. Drug treatment for acute and chronic causes of aggression will also be discussed.
Presenter: Judy L. Curtis, Pharm.D., University of Maryland
Location: Grand Ballroom, Salon B

2:00 - 3:50 • *Continuing Education ~ Diabetes: Updates in Therapy*
Presenter: Lynn McPherson, Pharm.D., University of Maryland
Location: Conference 1, 2, 3

3:00 - 3:50 • *Continuing Education ~ ADHD*
This session will update the pharmacist on the signs and symptoms of ADHD. Discussion will focus on the use of stimulants and other agents for management of the disorder as well as side effects and drug interactions.
Presenter: Mary C. Borovicka, Pharm.D., University of Maryland
Location: Grand Ballroom, Salon B

3:50 - 4:00 • *Beverage Break*
Location: Terrace Lobby

4:00 - 5:00 • *Continuing Education ~ Stress Management — How to Catch Your Breath When You're Losing Your Mind*
Changes in organizations and increasing work demands multiply stress. This program is filled with humor and useful ideas to teach attendees proven techniques to reduce stress, ways to relax under pressure, how to identify "good" vs. "bad" stress, and how to achieve more balance in their lives.
Presenter: Greg Risberg, M.S.W., Consultant
Location: Conference 1, 2, 3

6:30 - 9:00 • *Annual Crab Feast*
Admission by ticket only
Location: Phillips Crab House
2004 Philadelphia Avenue

MONDAY, JUNE 15

7:00 - 5:00 • *Registration*
Location: Terrace Lobby

7:00 - 9:00 • *Breakfast*
Location: Terrace Lobby

7:00 - 9:00 • *Trustee Meeting/Breakfast*
Sponsored By: *Pharmacia & Upjohn*
Location: Captain's Quarters

8:00 - 9:50 • *Continuing Education ~ Hormone Replacement Therapy*
Recently approved medications provide clinicians and patients with exciting options for managing patients with osteoporosis. This presentation will discuss the efficacy and toxicity of estrogens, alendronate and calcitonin for the prevention and treatment of osteoporosis. Recommendations for population-based management will be reviewed.
Presenter: Catherine Cooke, Pharm.D., University of Maryland
Location: Conference 1, 2, 3

8:30 - 10:00 • *SAMPA Breakfast/Business Meeting*
Location: Horizons Restaurant

9:50 - 10:00 • *Beverage Break*
Location: Terrace Lobby

10:00 -12:00 • *House of Delegates*
Resolutions to be considered by the House during this session must be submitted to House Secretary, Robert J. Boerner, by Sunday, June at 5:00 p.m.
Location: Conference 1, 2, 3

12:00 -1:30 • *Lunch and Continuing Education ~ Humor, Hugs and Hope!*
This positive and upbeat presentation will help attendees find more humor in their lives, understand the importance of touch in comforting and sustaining them, and strengthen their sense of hop It will energize those who attend and help them see the world and their place in it in a more positive way.
Presenter: Greg Risberg, M.S.W., Consultant
Location: Crystal Ballroom Hall 1

1:30 -3:20 • *Continuing Education ~ Pneumonia—Management in the Ambulatory and Hospital Settings*
This lecture will cover the clinical features of community and hospit acquired pneumonia and the approach to management. The variou antibacterial options for therapy will be presented along with a rational approach to product selection.
Presenter: Gary Smith, Pharm.D., FASHP, FCCP, University of Marylan
Location: Conference 1, 2, 3

3:20 - 3:30 • *Beverage Break*
Location: Terrace Lobby

3:30 -5:30 • *Continuing Education ~ Ethics*
Do you think you are an ethical pharmacist? This program will review commonly accepted bioethical principles such as beneficenc nonmalefience, autonomy, veracity, fidelity, distributive justice, and sanctity of life and demonstrate their role in pharmacy practice. Examples will be actively illustrated. Audience participation encourage
Presenter: Bethany DiPaula, Pharm.D., BCPP, University of Maryland
Location: Conference 1, 2, 3

7:00 -7:30 • *Banquet Reception*
It wouldn't be a convention without the pre-dinner cocktail reception Plenty of hors d'oeuvres will be the beginning of a festive evening.
Location: Grand Ballroom, Salon B

7:30 -9:30 • *Awards Banquet*
Celebrate the end of another fun-filled MPhA Convention at our Annual Awards Banquet. We will be honoring the 1998 MPhA Award Recipients as well as our new officers and trustees. Don't forget to sig up for a table seat at the MPhA Convention Registration Desk by 5:00 p.m. on Monday. Admission by ticket only.
Sponsored By: *McKesson Drug Company*
Location: Grand Ballroom, Salon A

TUESDAY, JUNE 16

7:00 - 11:00 • *Registration*
Location: First Floor Lobby

7:00 - 9:00 • *Breakfast*
Location: Grand Ballroom, Salon A

8:00 - 10:00 • *Continuing Education ~ Herbal Medication*
This program will review popular herbal remedies, their medicinal uses, and how they compare to traditional pharmaceuticals. Attendees will also learn useful ways in which pharmacists can begin to integrate herbs into the traditional pharmacy practice.
Presenter: Brian Sanderoff, R.Ph.
Sponsored by: *Modern Apothecary*
Location: Grand Ballroom, Salon B

Maryland Pharmacists Association

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Deadline: Monday, June 1, 1998

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(Check all that apply)	☐ Sat ☐ Sun ☐ Mon ☐ Tue		
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Interactions...

Wrapping Up the Semester at the School of Pharmacy

David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

On May 22, 1998 in the Baltimore Arena, 115 students received the Doctor of Pharmacy Degree from President David Ramsay. Honored at commencement was Harold E. Chappelear, President and CEO of University Pharmaceuticals of Maryland, who received the Honorary Degree Doctor of Laws. Mr. Chappelear has devoted his business and professional life to fostering the growth of the profession of pharmacy and to fostering productive relationships between the pharmaceutical industry and pharmacy practice. Earlier in the day, Dr. Georges Benjamin, Deputy Secretary for Public Health Services, Department of Mental Health and Hygiene for the State of Maryland, addressed the graduates at the School's private Convocation in Hunt Valley on roles for the pharmacists in public health and preventive services.

The Maryland General Assembly has approved a funding plan for emergency poisoning services and poison prevention activities for the state of Maryland. The plan reinforces the role of the Maryland Poison Center as the State of Maryland's official poison center. Effective July 1, the General Assembly has appropriated more than $1 million in annual funding to the School of Pharmacy in support of the Maryland Poison Center. This appropriation will both increase and make permanent the temporary fixes that the Center has been dealing with over the last few years. It will, at last, provide MPC with the resources it needs to assure all citizens of Maryland that its excellent services are available.

The General Assembly also provided $3 million to permit the School to construct a temporary classroom building on the northwest corner of Fayette and Pine Streets. The new classrooms and laboratories to be constructed will ease the space crunch that has been severe since the major enrollment increases associated with the Pharm.D. program and the Non-traditional Pharm.D. Pathway. The appropriation will also permit the construction of permanent faculty research laboratories within Pharmacy Hall.

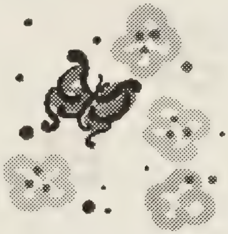
Both projects are stop gap measures until the state is able to construct permanent buildings to meet the School's teaching and research needs. In addition, Pharmacy Hall and the Health Sciences Facility Phase II are scheduled to receive planning money from the state in the year 2004.

Even with the new temporary building, our space needs are severe. We have recently been assigned additional floors in the 100 N. Greene Street and Century Buildings. This dispersing of our faculty and students makes it difficult to run the pharmacy programs efficiently and effectively. We are looking for ways to get our permanent building constructed more rapidly.

April 24th was the date of a marvelous celebration in honor of the many years of contributions of Dee and Bill Kinnard. More than 130 guests from around the nation joined the Kinnards at the Harbor Court Hotel for an elegant evening of music, dining, and tributes. Planned by Emeritus Professors Ralph Blomster and Ralph Shangraw, the event featured the presentation of an oil painting of Dean

Kinnard to the School of Pharmacy. The portrait was painted by Mr. Dan Thompson who trained at the Corcoran Gallery of Art in Washington, DC. The painting will be hung in Pharmacy Hall. The Kinnards plan to continue to reside in Baltimore.

Spring Break at the School of Pharmacy is usually a time for faculty to take a deep breath, catch up, and prepare for the second half of the semester. This year, however, more than 50 of the School's faculty traveled to Berkeley Springs, West Virginia, for a three-day retreat. The focus was on student assessment. Specifically, how to better evaluate Pharm.D. students to make sure that they are able to integrate material and achieve the desired outcomes of pharmaceutical care. The faculty worked on the courses entitled "*Integrated Science and Therapeutics*," a 15-credit hour sequence across the third year. The course is unusual in that it involves more than 30 faculty members. Coordination of instruction and assessment is essential if the objectives are to be met.



Getting away in the West Virginia hills also gave our faculty a good opportunity to get to know each other better, especially given the rapid growth during the last few years.

In early June, a team of five faculty members attended the American Association of Colleges of Pharmacy Institute on pedagogy. About 50 schools participate in this 4-day session at the Xerox Training Center in Leesburg, Virginia each year. The focus is on teaching and improving our curriculum. It is one of the ways that our faculty make sure that our professional education programs, including experiential learning, continue to excel.

Doctor of Pharmacy Degree

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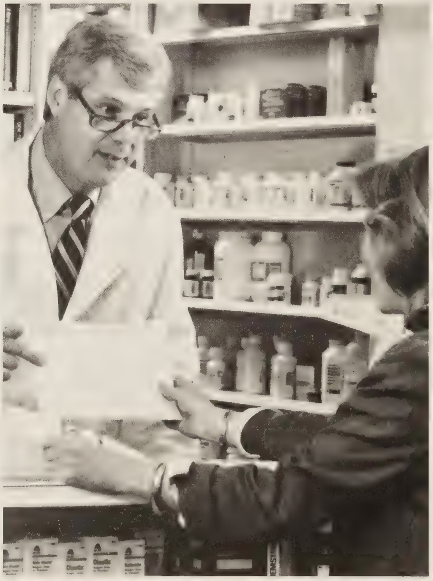

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Clozapine Induced Neuroleptic Malignant Syndrome (NMS)

Dawn Johnson
4th Year Pharm.D. Student
University of Maryland School of Pharmacy

Schizophrenia is a complex disorder which may have multiple etiologies that may be based on biological, psychosocial, and environmental influences.[1] It afflicts approximately 10% of the United States' disabled population and about 2.5% of our total annual health care costs are spent on schizophrenia. The DSM-IV Criteria for Schizophrenia include characteristic symptoms, social dysfunction, duration, schizo affective disorder and mood disorder exclusion, substance/general medical condition exclusion, and relationship to a pervasive development disorder. Pharmacotherapy is used to decrease the risk of harm to the patient or of his or her risk to harm others.

Antipsychotic agents include low potency agents such as chlorpromazine, high potency agents such as haloperidol, and atypical agents such a clozapine. Clozapine has been approved by the Food and Drug Administration for the treatment of resistant schizophrenia or when adverse effects preclude the use of other antipsychotic agents.[1] Clozapine use is contraindicated in patients with a history of myeloproliferative disorders, bone marrow suppression, or clozapine induced agranulocytosis. There have been various side effects related to the use of clozapine, some of these include tachycardia, hypotension, fever, headache, hypertension, blurred vision, abdominal discomfort, dry mouth, agranulocytosis, and NMS. Although agranulocytosis and NMS account for approximately 1% of side effects, these reactions are potentially fatal and should be carefully monitored when patients are using clozapine.

NMS is rare, but may be a potential lethal adverse effect of clozapine use. NMS has been shown to be a self-limiting syndrome which develops over 24-72 hours and lasts for 5-10 days after discontinuation of the offending psychotropic agent.[3] The syndrome may surface within two weeks of the initiating a psychotropic drug or after an increase in the dose of the drug. Diagnostic criteria of NMS include altered mental status, muscular rigidity, fever (without other causes), autonomic dysfunction (tachycardia, diaphoresis, alterations in blood pressure, tachypnea, and incontinence), and elevations of CPK.[4] Various studies have shown that clozapine has the propensity to induce NMS in some patients. A few of the predisposing factors which link clozapine to causing NMS include dehydration, physical exhaustion, use of high potency neuroleptics (e.g., haloperidol, fluphenazine), concurrent lithium therapy, male gender, and previous episodes of NMS. Miller and associates describe the case of a 50 year old who was diagnosed with catatonic schizophrenia in 1966.[5] This patient had previously had three incidences of NMS. The patient reached a clozapine dose of 500mg/day. After 8 months of using clozapine, the patient presented with fever, severe rigidity, elevated CPK, fluctuating blood pressure, tachycardia, altered conscious, and diaphoresis. The clozapine was discontinued and I.V. dantrolene was initiated. The muscle rigidity, diaphoresis, and myoglobinuria resolved. The delayed onset of NMS with clozapine in this patient is quite consistent with his past history where he took other antipsychotics for 6 to 12 months before developing NMS.

In 1991, Anderson and Powers studied a 26 year old Caucasian female who was started on clozapine 25 mg twice daily and increased to a dose of 250 mg/day.[6] Five weeks after the initiation of clozapine, the patient experienced debilitating pain in her calves, general malaise, chills, fever, diaphoresis, increased heart rate, proximal weakness and rigidity of both lower extremities, and an elevated CPK and ESR. Clozapine was discontinued and her signs and symptoms of lower extremity stiffness, leg pain, nausea, and vertigo subsided over a 96 hour period. Both her CPK and ESR normalized after 8-11 days after discontinuation of clozapine. The patient was rechallenged with clozapine and after a 6 month period, the patient continued to do well on 375 mg/day of clozapine but was noted to have a slight temperature during this time. When a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully monitored.[2] The authors concluded that clozapine is a major breakthrough in treatment-resistant schizophrenia. Optimal treatment of patients is based on the early recognition of NMS signs and symptoms.

Dasgupta and Young describe the case of a 30 year old white male who began to experience cyanosis, nailbed pallor, decreased responsiveness, increased temperature and pulse, diaphoresis, severe upper extremity cogwheel rigidity, and an increase in white blood cells and serum iron after a third dose of clozapine 25 mg.[7] The drug was discontinued and the patient's signs and symptoms were resolved. Three days after discontinuation of clozapine the symptoms reappeared. The patient was given lorazepam to treat the catatonic symptoms. The authors noted that this patient may have been at risk for the development of NMS because of his history of mental retardation. The authors recommend that clinicians monitor clozapine treated patients for signs and symptoms of NMS.

In the previous case, the mail experienced an increase in serum iron levels. In 1991, Rosebush and Mazurek suggested that the reduction in serum iron may be important in the pathogenesis of NMS.[8] Iron is a cofactor of tyrosine hydroxylase which is the rate-limiting enzyme in norepinephrine and dopamine synthesis. The authors determined that there may be a link to a decrease in D_2 receptor function.

NMS continues to be a possible fatal syndrome which tends to be under diagnosed. Clozapine has been shown to cause NMS in various patients. Clozapine has been found to be more effective than conventional neuroleptics in controlling the positive and negative symptoms. Patient response to clozapine is patient specific. Patients should be monitored closely to avoid the NMS fatalities which are induced by clozapine use.

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8. Rosebush P, Mazeruk M. Serum iron and neuroleptic malignant syndrome. *Lancet.* 1991;338:149-51.

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Counseling Notes for Pharmacists

Foot Service

The human foot is an intricately designed structure containing 26 bones, 33 joints, and more than 100 ligaments, muscles and tendons. The two feet contain about a quarter of all the bones in the body and more than 500,000 sweat glands. Given this complexity, it is not surprising that there are about 300 different foot ailments. Some are hereditary, others are secondary to medical conditions such as circulatory disorders, diabetes or arthritis—but most are a result of the cumulative impact of a lifetime of abuse and neglect.

Research indicates that about 75% of Americans experience some type of foot problem, but few individuals seek medical assistance because they accept foot discomfort and pain as "normal." Women have four times as many foot problems as men, primarily because of wearing shoes that have high heels.

Feet tolerate a tremendous load of pressure: for example, there are times when the pressure on the feet during walking exceeds one's body weight; when running, the pressure can be three or four times one's weight. An average day of walking brings a force equal to several hundred tons to bear on the feet. According to the American Podiatric Medical Association, the average person takes between 8,000 and 10,000 steps each day. We can cover several miles in a day. This adds up to about 115,000 miles in a lifetime—more than four times the circumference of the globe!

Shoes that fit properly are essential; it is best if they have a firm sole and soft upper portion, as well as good arch support. Walking is the best exercise for the feet, but wearing shoes that fit poorly or provide inadequate support can obviate the benefits of walking. Periodic foot examinations, especially as a person ages, are advisable.

The three most common foot problems are infections, (including athlete's foot, fungal infections and plantar warts), corns and calluses, and toenail problems. About 5% (or 11 million) of people in the U.S. contact foot infections each year; 5% have ingrown toenails or other nail problems; and 5% develop corns and/or calluses. Of these common ailments, corns and calluses are the least likely to be treated professionally and are, therefore, the most likely to persist.

Podiatric physicians are a major source of footcare services, providing 367% of all foot care, with orthopedic physicians providing 13% and physical therapists about 11%. In a single year, approximately 14 million patients made more than 55 million visits to podiatrists' offices.

As with many other ailments, prevention is the most important part of a treatment strategy for foot problems—and a pharmacist is in an ideal position to offer advice and counseling about care of the feet.

For more information, contact the American Podiatric Medical Association at 1-800-FOOTCARE.

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Health Tips for Patients

Fantastic Feet

Your feet contain about one-fourth of all the bones in your body—and more than 500,000 sweat glands! Each foot has 26 bones, 33 joints, and more than 100 ligaments, muscles and tendons. There are about 300 different foot ailments, and almost 75% of Americans have some type of foot problem during their lifetime. Here are some tips for keeping your feet healthy:

- Be sure your feet are measured every time you buy shoes—our feet grow with age.
- Wear shoes that have been professionally fitted to your specific foot size and shape.
- Take frequent walks to keep your feet exercised.
- When taking a walk, always wear shoes designed especially for walking. The shoes should:
    - Have a firm sole and soft upper for appropriate flexion.
    - Provide adequate support for arches and soles.
    - Be made of material that allows airflow to the feet.
- Avoid going barefoot (wear shower-shoes at the gym).
- Bathe feet daily in lukewarm water with a mild soap; moisturize to soften heels, calluses and corns.
- Never cut corns or calluses with a razor or other sharp instrument—a pumice stone is preferable and safer.
- Trim toenails straight across to avoid ingrown toenails.
- Use over-the-counter foot products *only* with the advice of your own pharmacist or podiatrist.

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83% **of men taking PROPECIA in vertex studies maintained or increased hair count (v. 28% placebo) at Month 24. Early benefits of slowing hair loss can be seen at Month 3 based on patient self-assessment.**

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66% **of men taking PROPECIA in vertex studies had visible hair regrowth (v. 7% placebo) based on global photographic assessment. In addition, investigators rated 81% of patients as improved (v. 46% placebo).**

Excellent safety profile

<2% **Each drug-related adverse event occurred in <2% of men.**

Adverse Events at 12 Months	PROPECIA 1mg (N=945)	Placebo (N=934)
Decreased libido	1.8%	1.3%
Erectile dysfunction	1.3%	0.7%
Ejaculation disorders (Primarily decreased ejaculate volume)	1.2%	0.7%

Patients completed a self-administered questionnaire to detect more subtle changes in sexual function; results were consistent with this table. No significant difference was seen in overall satisfaction with sex life.

No drug interactions of clinical importance have been identified.

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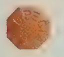

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. (See also WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; and PRECAUTIONS, *Information for Patients* and *Pregnancy.*) In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

Hypersensitivity to any component of this medication.

WARNINGS

PROPECIA is not indicated for use in pediatric patients (See PRECAUTIONS, *Pediatric Use*) or women (See also PRECAUTIONS, *Information for Patients* and *Pregnancy*).

EXPOSURE OF WOMEN–RISK TO MALE FETUS

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; PRECAUTIONS, *Information for Patients* and *Pregnancy.*)

PRECAUTIONS

General

Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Information for Patients

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; PRECAUTIONS, *Pregnancy.*)

Drug/Laboratory Test Interactions

In clinical studies with PROPECIA in men 18-41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at Month 12. When finasteride is used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Until further information is gathered in men >41 years of age without BPH, consideration should be given to doubling the PSA level in men undergoing this test while taking PROPECIA.

Drug Interactions

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no interactions were found.

Other concomitant therapy: Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, α-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

Impairment of Fertility

Sexually mature male rabbits treated with finasteride at 80 mg/kg/day (4,344 times the estimated human exposure) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 80 mg/kg/day of finasteride (488 times the estimated human exposure), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats but is not relevant in man.

Pregnancy

Teratogenic Effects: Pregnancy Category X

See CONTRAINDICATIONS.

PROPECIA is not indicated for use in women.

Administration of finasteride to pregnant rats at doses ranging from 100 μg/kg/day to 100 mg/kg/day (5-5,000 times the recommended human dose of 1 mg/day) resulted in dose-dependent development of hypospadias in 3.6 to 100% of male offspring. Pregnant rats produced male offspring with decreased prostatic and seminal vesicular weights, delayed preputial separation, and transient nipple development when given finasteride at ≥30 μg/kg/day (≥1.5 times the recommended human dose of 1 mg/day) and decreased anogenital distance when given finasteride at ≥3 μg/kg/day (one-fifth the recommended human dose of 1 mg/day). The critical period during which these effects can be induced in male rats has been defined to be days 16-17 of gestation. The changes described above are expected pharmacological effects of drugs belonging to the class of Type II 5α-reductase inhibitors and are similar to those reported in male infants with a genetic deficiency of Type II 5α-reductase. No abnormalities were observed in female offspring exposed to any dose of finasteride *in utero*.

No developmental abnormalities have been observed in first filial generation (F_1) male or female offspring resulting from mating finasteride-treated male rats (80 mg/kg/day; 488 times the human exposure) with untreated females. Administration of finasteride at 3 mg/kg/day (150 times the recommended human dose of 1 mg/day) during the late gestation and lactation period resulted in slightly decreased fertility in F_1 male offspring. No effects were seen in female offspring. No evidence of malformations has been observed in rabbit fetuses exposed to finasteride *in utero* from days 6-18 of gestation at doses up to 100 mg/kg/day (5000 times the recommended human dose of 1 mg/day). However, effects on male genitalia would not be expected since the rabbits were not exposed during the critical period of genital system development.

The *in utero* effects of finasteride exposure during the period of embryonic and fetal development were evaluated in the rhesus monkey (gestation days 20-100), a species more predictive of human development than rats or rabbits. Intravenous administration of finasteride to pregnant monkeys at doses as high as 800 ng/day (at least 750 times the highest estimated exposure of pregnant women to finasteride from semen of men taking 1 mg/day) resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a very high dose of finasteride (2 mg/kg/day; 100 times the recommended human dose of 1 mg/day or approximately 12 million times the highest estimated exposure to finasteride from semen of men taking 1 mg/day) to pregnant monkeys resulted in external genital abnormalities in male fetuses. No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

Nursing Mothers

PROPECIA is not indicated for use in women.

It is not known whether finasteride is excreted in human milk.

Pediatric Use

PROPECIA is not indicated for use in pediatric patients. Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Clinical Studies for PROPECIA (finasteride 1 mg) in the Treatment of Male Pattern Hair Loss

In controlled clinical trials for PROPECIA of 12-month duration, 1.4% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably or definitely drug-related (1.6% for placebo); 1.2% of patients on PROPECIA and 0.9% of patients on placebo discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably or definitely drug-related in ≥1% of patients treated for 12 months with PROPECIA or placebo, respectively: decreased libido (1.8%, 1.3%), erectile dysfunction (1.3%, 0.7%) and ejaculation disorder (1.2%, 0.7%; primarily decreased volume of ejaculate:[0.8%, 0.4%]). Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in all men who discontinued therapy with PROPECIA due to these side effects and in 58% of those who continued therapy.

In a study of finasteride 1 mg daily, in healthy men, a median decrease in ejaculate volume of 0.3 mL (-11%) compared with 0.2 mL (-8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median decreases of approximately 0.5 mL (-25%) compared to placebo in ejaculate volume but this was reversible after discontinuation of treatment.

In the clinical studies with PROPECIA, the incidences for breast tenderness and enlargement, and for hypersensitivity reactions in finasteride-treated patients were not different from those in patients treated with placebo.

Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR (finasteride 5 mg) in the Treatment of Benign Prostatic Hyperplasia

In controlled clinical trials for PROSCAR of 12-month duration, 1.3% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably or definitely drug-related (0.9% for placebo); only one patient on PROSCAR (0.2%) and one patient on placebo (0.2%) discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably or definitely drug-related in ≥1% of patients treated for 12 months with PROSCAR or placebo, respectively: erectile dysfunction (3.7%, 1.1%), decreased libido (3.3%, 1.6%) and decreased volume of ejaculate (2.8%, 0.9%). The adverse experience profiles for patients treated with finasteride 1 mg/day for12 months and those maintained on PROSCAR for 24 to 48 months were similar to that observed in the 12-month controlled studies with PROSCAR. Sexual adverse experiences resolved with continued treatment in over 60% of patients who reported them.

Adverse Effects Reported in Post-Marketing Experience for PROSCAR (finasteride 5 mg)

Breast tenderness and enlargement, as well as hypersensitivity reactions, including lip swelling and skin rash have been reported.

DOSAGE AND ADMINISTRATION

The recommended dosage is 1 mg once a day.

PROPECIA may be administered with or without meals.

In general, daily use for three months or more is necessary before benefit is observed. Continued use is recommended to sustain benefit. Withdrawal of treatment leads to reversal of effect within 12 months.

For more detailed information, please read the complete Prescribing Information.

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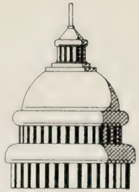
1998 Legislation Affecting Pharmacy

Bills Introduced in the Maryland General Assembly



Bill	Title	Sponsor/Committee	Description	Action
House Bill 267	Administration of Drugs	Owings/Environmental Matters	Permits administration of drugs under certain circumstances	Failed
House Bill 1187	Collaborative Drug Therapy Management	Owings/Environmental Matters	Authorizes collaborative practice agreements under certain circumstances	Failed
House Bill 1062	Drug Storage and Shipment Safety Act	Klausmeier, Elliott, Hughes, Stull/Environmental Matters	Regulates delivery of prescriptions when the medication is not given directly to patient or agent of patient	Passed House and Senate
Senate Bill 412	DrugStorage and Shipment Safety Act	Bromwell/Economic and Environmental Affairs	Regulates delivery of prescriptions when the medication is not given directly to patient or agent of patient	Passed Senate and House
House Bill 704	Retroactive Denials of Reimbursement	Donoghue/Economic Matters	Prohibits retroactive denials of reimbursement	Failed
Senate Bill 444	Retroactive Denials of Reimbursement	Dorman, Rubin/Finance	Prohibits retroactive denials of reimbursement	Failed
Senate Bill 38	Durable Medical Equipment Suppliers - MMAP	Baker/Finance	Increasing the listing of "Historic Providers" with no apparent effect on pharmacy	Passed Senate and House
House Bill 173	Maintenance Drug Prescriptions	Frank et al/Economic Matters	Repeals termination date for maintenance drug supply of 90 day supply	Passed House and Senate
Senate Bill 235	Maintenance Drug Prescriptions	Astle, Kelly, Hollinger, Derr, Stolzfus/Finance	Repeals termination date for maintenance drug supply of 90 day supply	Passed Senate and House
House Bill 139	Unspent Special Funds	Gordon, Healy, Hixon, Hurson	Requires use of some funds from regulatory boards to give to developmentally disabled	Failed
House Bill 803	Allocate Funds for Project Reserve	Rosenberg/Environmental Matters	Allows regulatory boards to use monies from reserves for specific expenses	Failed

Senate Bill 352	Allocate Funds for Project Reserve	Hoffman, Hollinger/Budget and Taxation and Economic and Environmental Affairs	Allows regulatory boards to use monies from reserves for specific expenses	Failed
House Bill 765	Task Force on Pharmacy Technicians	Goldwater, Bozman/ Environmental Matters	Establish a task force on pharmacy technicians	Failed
House Bill 444	Physical Therapist Scope of Practice	Owings/Environmental Matters	Authorizes physical therapists to prescribe and dispense topical agents	Failed
Senate Bill 363	Physical Therapist Scope of Practice	Collins/Economic and Environmental Matters	Authorizes physical therapists to prescribe and dispense topical agents	Failed
House Bill 1019	Nurse Psychotherapists Authority to Prescribe Medications	Goldwater, Nathan-Pulliam, Klausmier/Environmental Matters	Authorizes nurse psychotherapists to prescribe certain medications	Failed
House Bill 1094	Physician Assistants - Delegated Prescription Authority	Redmer/Environmental Matters	Authorizes physicians to delegate prescriptive authority to physicians under specified circumstances	Failed
Senate Bill 782	Advisory Committee on Home-Based Health Care Services	Astle/Finance	Establishes advisory committee on home-based health care services in DHMH with pharmacist member	Passed Senate and House
House Bill 1408	Health Carriers Drug Substitution Notice	Bozman/Economic Matters	Requires pharmacist to notify patient if either therapeutic or generic drugs are substituted	Failed
House Bill 2	Consolidates Health Care Regulatory duties under HCACC	Goldwater et al/Environmental and Economic Matters	Allows HCACC to exempt any health occupations class	Passed House and Senate
House Bill 383	Health Occupations Boards - Disclosure of Information	Chairman Economic Matters/Economic Matters	Requires certain health occupations boards to disclose information about possible insurance fraud	Failed

Federal Law Update

Medicare Diabetes Benefit: HCFA is proceeding with implementation of this new coverage of diabetes supplies for all Medicare enrollees with diabetes, and educational services from qualified providers. Implementation dates are not finalized at this point, but the law says blood-testing strips are covered as of January 1, 1998 and other items and services are covered as of July 1, 1998.

HCFA Mandated Surety Bonds: The 1997 Balanced Budget Agreement included a new requirement for Medicare durable medical equipment (DME) suppliers and home health care agencies. Originally it called for all Medicare Home Health Care Agencies and DME suppliers to secure a surety bond for a minimum of $50,000 by January 1, 1998. That date was postponed until at least February 27, 1998. On January 5, 1998, HCFA released regulations for home health care agencies as a Final Rule with a comment period. HCFA also stated that it plans to issue a proposed regulation on surety bonds for DME suppliers early in 1998. This regulation would not take effect until a final rule is published following a period of public comment.

Legislation has been introduced by Senator Byron Dorgan of North Dakota that would exempt pharmacies and pharmacists from the surety bond requirement (S. 1680). Representatives Berry from Arkansas and Pallone from New Jersey have introduced similar legislation (H.R. 3284) in the House.

HCFA Additional Standards to Qualify as a Durable Medical Equipment (DME) Medicare Supplier: This proposed rule would establish standards in addition to those mandated by the Social Security Amendments of 1994 before a supplier could receive payment from the Medicare Program. Such standards are related to State and Federal licensure requirements, maintaining a physical facility on an appropriate site, proof of appropriate liability insurance and other standards the Secretary may specify. See 42 CFR Part 424 [HCFA-1864-P] RIN 0938-AH19.

H. R. 3284: To amend title XVIII of the Social Security Act to exempt pharmacists licensed under State law from surety bond requirements under the Medicare Program. Referred to the Subcommittee on Health and Environment on March 23, 1998.

House Resolution 151: To encourage consumers to consult with their pharmacists in connection with the purchase and use of over-the-counter drugs. Referred to the Subcommittee on Health and Environment.

H. R. 1060: To amend the Food, Drug and Cosmetic Act to authorize compounding of drugs and devices under certain circumstances. Referred to the Subcommittee on Health and Environment.

H. R. 1525: To assure that a health plan offering mail order prescription drug coverage also offers non-mail order coverage through a local pharmacy (defined as a pharmacy located within 5 miles of an urban resident and 10 miles of a non-urban resident). Referred to the Subcommittee on Health and Environment.

H. R. 1218: To amend title XVIII of the Social Security Act to provide for coverage of pharmaceutical care services under Medicare Part B. Referred to the Subcommittee on Health and Environment.

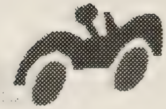
H. R. 1201: To amend title XVIII of the Social Security Act to establish a medication evaluation and dispensing system for Medicare beneficiaries, to improve the quality of pharmaceutical services received by the elderly and disabled and to reduce the instances of adverse reactions to prescription drugs by Medicare beneficiaries. Referred to the Subcommittee on Health and Environment.

Senate Resolution 99: To encourage consumers to consult with their pharmacists in connection with the purchase and use of over-the-counter drug products. Referred to the Committee on Labor and Human Resources.

S. 1368: To provide individuals access to their health information, ensure privacy of personal medical records and health care-related information, impose criminal and civil penalties for unauthorized use of this information and to provide for the strong enforcement of these rights. Committee on Labor and Human Resources hearings held February 26, 1998.

Federal Law Update as of April 27, 1998

The Road Less Traveled Is Now A Paved Highway



by

Joanne M. Doyle, R.Ph, Board Member
Massachusetts Pharmacists Association.

It is a Monday morning at the local 24-hour chain pharmacy. As you stand in line to drop off your child's Amoxicilin prescription you look at the wall where the name plates of the pharmacist are displayed. You cannot help but notice that all of the individuals are female. You think back twenty-five years to when you were a child when your own mother brought your prescription into the corner drugstore that was employed by only men. Times have really changed you think. Then you look a little closer to the signs, "Wow, one of the women is even the manager. That's great, too."

The faces of pharmacy have certainly changed in twenty five years. In 1972, less than 30% of the graduating classes from pharmacy schools were female. Now more than 60% of the graduates are female.

Why do women choose pharmacy? Some women chose pharmacy because they liked the sciences and wanted to help individuals in an area other than nursing. Other women had fathers who owned pharmacies and wanted to pursue that same track. Margaret Dempsey-Clapp, Director of Pharmacy at Massachusetts General Hospital, chose pharmacy because as a youth she saw a drug interaction occur in a family member and thought that if she was a pharmacist she could help others by preventing such occurrences.

Certainly the reasons for which women choose pharmacy are numerous but what type of impact have women made on the profession? How did they accomplish these goals? What obstacles did they overcome? What is in the nature of women that have made pharmacy better? How do they strive to be better, what skills do they need? How have they made the lives of women pharmacists and those of their patients better?

Had it not been for the precedents set by women pharmacists practicing in the 60's and 70's their involvement in the profession may not be where it is today. Several women have worked very hard to further the profession and in the process have boosted the status of women in pharmacy.

Angele D'Angelo is one such individual whose role in 30 years of pharmacy has gone unprecedented. After graduating from St. John's University in New York in the early 60's, she and her husband opened their own pharmacy. It was unheard of at that time that a woman work in a community pharmacy but she gained the respect and trust of patients as she pioneered pharmaceutical care. At the "pharmacy office," patients would have their prescriptions filled but not before they were asked a medical history, drug allergies and other relevant information usually obtained at a doctor's office. D'Angelo would review each patient's profile and call doctors' offices for drug allergies or OTC interactions. Initially the doctors were surprised that a woman pharmacist was calling but once they realized the impact she made on the community they had respect for her. In the course of the next twenty five years, D'Angleo expanded her role of pharmacist to educator, administrator, and leader. Having started one of the first internship programs in the country at St. John's University, she eventually became Dean of the College of Pharmacy. She was also the first woman delegate for APhA and became the Vice President of APhA in 1977. She was also the first woman on the Board of Pharmacy in New York. Probably one of her most influential positions has been the editor-in-chief of U.S. Pharmacist. When offered the position eight years ago, D'Angleo saw this as the perfect opportunity to take advantage of what she had been working for so long. High leadership positions for women had been few and far between and now here was her chance to influence the profession of pharmacy on a larger scale. Since taking the post in 1989, Ms. D'Angelo has improved the clinical applications of the publication while including extensive articles on women's health.

Another woman aiding the woman's cause was Jean Matuszak, a medical chemistry professor at the University of the Pacific. She too, was one of few women in a predominantly male field. However, she was active with APhA and helped initiate the

Task Force for Women's Issues. She worked with the Office of Women's Affairs to promote more studies into women's issues as well as push for the nominations of women for leadership positions. In 1991, Matuszak also designed a women's leadership survey for the state associations. The survey included questions about practice setting, how many women were presidents of associations and whether a task force or committee was established for women's issues in that state. In climbing her own pharmacy ladder, Matuszak did not experience the usual gender barriers. The individuals she worked with (mostly men) appointed her to department chair and other positions based on credentials. She said her peers judged her on merit and not gender. Matuszak was fortunate as she did not have to deal with the hurdles that some other women encountered.

Obstacles these women have overcome to achieve their positions have paved a way for future women pharmacists. Some women pharmacists of today may not understand what their predecessors endured in overcoming barriers. Something as accepted as a woman working in a community pharmacy rarely happened 25 years ago. Not only was a woman community pharmacist not accepted by the general public, they were not accepted at time by members of the other medical professions. In an article written in American Druggist in 1974, one woman pharmacist said, "I had one physician who refused to give me a prescription until I gave him my credentials of graduation and registration. He then gave me the prescription and a half hour later came over to the pharmacy to see if I really existed." High leadership positions for women was not widely accepted at this time as well. When she was an officer for the California State Association in the 1970's, Mary Rings was greeted with comments like "Well, little girl what can you tell us..." when she gave testimony for product selection for the state. With poise and composure she ignored the remarks and continued with her speech. Despite receiving condescending remarks and attitudes from others, these women continued to focus on their own assets to improve pharmacy and make it a better profession.

Articles that were written in the 1970's questioned whether women would be good for pharmacy. How ambitious were they? Are they assertive enough? How will they take care of a family? Other stereotypes that women were too emotional, talkative or "nit picky" also surfaced.

These traits, once considered liabilities have actually proven to be assets. Mary Rings speaks of her ambition as she climbed the pharmacy ladder, "you have to participate in your profession and that means by starting at the bottom and working hard." Rings started her career in hospital pharmacy and was active in her state association as Speaker of the House, Vice President, and President. She was also involved in APhA and worked her way up the ladder as a member of the board of trustees and in 1979 became the association's first woman president.

The antiquated notion that a woman would have difficulty balancing a career and family has been diminished. With the precedence set by women today, employers are no longer concerned about women's ability to balance both career and family. Having a family was an advantage for Angele D'Angelo since, "By being a mother, I became a better pharmacist." She understood where her patients, particularly women with children, were coming from and they respected her for it.

The emotional component along with being relationship oriented has strengthened the role of the pharmacist. One female pharmacist said she had a crying woman who was so appreciative that the pharmacist had taken the time to ask about her sick mother as well as offer alternatives for her home health care services. "Thank you for asking; you really do care," the patient remarked. As Kirk and Ohvall state in their 1973 APhA report "A woman pharmacist's inherent patience and understanding often engenders better rapport with sympathy-seeking patrons."

Since pharmacy is a detail oriented profession, women have applied their ability to be "nit picky" to aid their patients. Whether adjusting a dosage regimen based on the patient's serum creatine or watching for a cross sensitivity of penicillin and cephalosporin, pharmacists are meticulous. Although women were once considered to be overly particular, they have demonstrated that this trait is especially important when dealing with dosing regimens for pediatric, geriatric and chemotherapy patients.

Women pharmacists of today have learned from their predecessors. Women of today have learned how not to listen to the nay-sayers but rather focus on their strengths and learn from their liabilities. They have seen how to always have the desire to learn and keep an open mind. They have seen how their mentors worked together as a team. They have watched how personalities were evaluated in order to achieve the same goal. They have looked at women like Mary Rings who realized that life is not a spectator sport and that in order to make a difference, one has to be involved. Successful women pharmacists of today have seen these veteran women exhibit self-confidence and assertiveness when society stereotyped their positions. As a result women pharmacists of today are more accepted and respected than they were 25 years ago.

Although women, like Angele D'Angelo, Jean Matuszak, and Mary Rings, helped bring the presence of women in pharmacy to the forefront, most importantly they have helped academia, by becoming leaders in boards of pharmacy, associations, and publications. Women in pharmacy have made the lives of their colleagues and their patients better by focusing on their strengths and teaching others how to learn from their weaknesses. These women have taken the road "less traveled by and that has made all the difference."

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The Food and Drug Administration Modernization Act of 1997: Its Purpose and Intent

by Shelly Capps

On November 9, 1997, Congress passed the Food and Drug Administration Modernization Act of 1997 (Modernization Act) which includes a provision to protect pharmacists' rights to compound. The law was signed by President Clinton on November 21, 1997 and will be effective on November 21, 1998.

New section 503A amends the Federal Food, Drug and Cosmetic Act (FDC Act) to recognize that pharmacy compounding is legal. In addition it sets forth parameters for compounding practice. All compounding that is conducted within the specific parameters will be exempt from Food and Drug Administration's New Drug Applications (NDA) and Good Manufacturing Practices (GMP).

The Compounding Law: A Summation

New Drug Application Exemption

The compounding provision amends the Federal Food, Drug and Cosmetic Act exempting compounded drugs from the New Drug Application requirements. Congress and the FDA now recognize that compounding does not create an unapproved new drug and compounding pharmacists are not manufacturers.

Triad (Pharmacist-Patient-Practitioner) Relationship

The compounding provision preserves the triad relationship and provides for anticipatory compounding. According to the provision, a licensed pharmacist, who practices in either a state licensed pharmacy or in a federal facility, is authorized to compound a drug for an identified individual patient based on a valid prescription.

Bulk Drug Substances

The compounding provision provides for bulk drug substances that can be used to compound. Substances that are USP or NF or are components of an FDA approved product can be used to compound. Substances that do not meet either of these criteria must be present on a list of drug substances established by regulation through notice and comment rulemaking. To issue these regulations, the FDA must convene an advisory committee that must consist of the USP, the NABP, pharmacy, physician and consumer organizations and other experts to propose criteria for substances to be used in compounding. The criteria already established by Congress include historical use and medical literature. The advisory committee will propose other criteria to establish substances for use for compounding. The FDA and the advisory committee will then create a list of substances that can be used for compounding. This rulemaking process should take about one year. Congress intends that organizations will be able to petition FDA to add substances to this list.

Commercially Available Medications

The compounding provision provides for the compounding of commercially available medications if there is a change made to the medication that is significantly different from the commercial product. An example identified by Congress is a dye-free product. The bill defers to the prescriber to determine whether the change is significantly different for an individual patient. Under certain circumstances a pharmacist could compound a commercially available product.

Interstate Distribution

The compounding provision establishes a mechanism for the regulation of interstate distribution of compounded medications. The FDA and the National Association of Boards of Pharmacy will draft a Memorandum of Understanding (MOU) to provide for state boards to regulate and to accomplish two objectives:
1) commit the states to answer complaints from other states about interstate compounding;
2) commit the states to establish "safe harbors" for their pharmacists who are distributing

products in interstate commerce. A pharmacist living in a state that does not sign an MOU will be subject to FDA's "safe harbor" whereby compounded products may not exceed five percent of the total prescription orders dispensed or distributed by a pharmacy or physician.

Advertising/Promotion

The compounding provision prohibits the advertising and promotion of a particular drug product but provides for the advertising of compounding services.

The Implementation

The scope of the new legislation will be significantly affected by the various rulemakings authorized under the law, the MOU between the states and the FDA, and other actions taken by states and the FDA to interpret the provisions. In implementing this law, states should work to ensure that patients have access to appropriately compounded medications.

Clearly, this is the most significant piece of pharmacy legislation to pass Congress in recent years. Congress has recognized the importance of compounding. The law should be implemented as Congress intended as stated in the House/Senate Conference Report (House Report 105-399): "to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding."

This is a brief description of the Modernization Act. To be in compliance with the Act, all pharmacists and prescribers are encouraged to read the entire law - Section 127 of Public Law 105-115 Section 503A.

Shelly Capps is the executive director of the International Academy of Compounding Pharmacists (IACP). IACP represents approximately 1100 independent compounding pharmacists who are dedicated to increasing awareness of compounding because of its importance to quality health care. In addition, IACP members are committed to maintaining high standards of traditional pharmacy practice. The organization initiated efforts to pass compounding preservation legislation in 1994.

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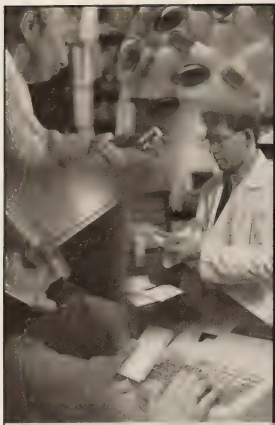

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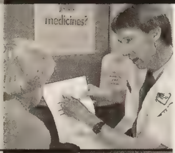

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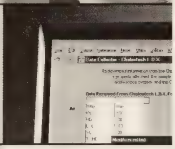

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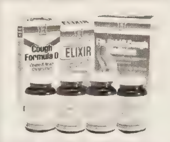

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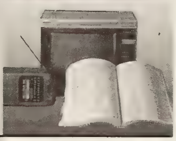

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Continuing Education for Pharmacists

Volume XV, No. 7

Patient Counseling: Prevention and Treatment of Skin Injuries; Part 1: Basic Concepts and the Itch Response

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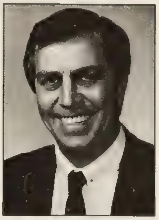
Goals. The goals of this lesson are to discuss common dermatologic conditions that are self-treatable with skin protectants, and to present information to use in counseling patients.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify physiologic considerations of the skin and the itch response;
2. identify the causes and etiology of the itch response;
3. exhibit knowledge of the treatment and means to prevent the itch response;
4. show an understanding of the pharmacologic actions and adverse effects associated with skin protectants and other drugs used to treat the itch response; and,

Gossel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5. demonstrate an ability to counsel patients on the self-medication of minor skin disorders.

The Skin

The largest and most versatile organ of the body, the skin of an average adult weighs approximately six pounds. It receives about one-third of the circulating blood volume. It also contains a rich network of nerve fibers that are sensitive to stimulation; thus, the skin can be a source of great discomfort when it is irritated.

Skin is elastic and rugged. Under normal conditions, it is self-regenerating.

Skin is constantly exposed to a broad assortment of environmental contaminants and self-applied abuse. It is stretched, scratched, rubbed, squeezed, twisted, gouged, picked, pierced, poked, scraped, soaked, burned, painted, marked, tattooed, sprayed, and shaved. Through it all, the skin generally remains healthy.

The skin consists of two primary layers: the epidermis (outer) and the dermis (lower). These lie directly upon a layer of adipose tissue (the hypodermis, subcutaneous layer) which provides cushioning and pliability, and serves as an effective thermal barrier. The dermis (corium) contains blood and lymph vessels, and nerve fibers. Nutrition is supplied to all layers of the skin through a rich vasculature located within the dermis. Sweat glands and sebaceous glands which open onto the skin's surface project deep into the dermis.

The epidermis is a thin cover composed of five distinct layers. From superficial to deep, these are the stratum corneum (horny layer), stratum lucidum (clear layer), stratum granulosum (granular layer), stratum spinosum (prickly layer), and stratum germinativum (regenerative layer). New epidermal cells constantly replace older cells that are being shed continuously.

The outermost layer, the stratum corneum, consists of flattened, dead (keratinized) cells. Keratin consists of approximately 20 percent water, compared to 70 percent in the stratum germinativum. It is this mantle of keratin that normally provides the skin's first line of defense against invasion by microbes and penetration by harmful chemicals. It guards against excessive moisture and electrolyte loss. Keratin also serves as a physical barrier to light and heat.

Skin Protectants

Humans have long applied a wide assortment of topical medicaments, prepared extemporaneously and commercially, to protect their skin from damage and prevent or treat irritation. More recently, various FDA panels of experts on OTC external products have evaluated many of these treatments. The skin

Table 1
Safe and Effective Skin Protectants

Ingredient	Concentration
allantoin	0.5-2%
aluminum hydroxide gel	0.15-5%
calamine	1-25%
cocoa butter	50-100%
colloidal oatmeal	----
dimethicone	1-30%
glycerin	20-45%
kaolin	4-20%
petrolatum	30-100%
shark liver oil	3%
sodium bicarbonate	1-100%
white petrolatum	30-100%
zinc acetate	0.1-2%
zinc carbonate	0.2-2%
zinc oxide	1-25%

protectants listed in Table 1 are considered to be safe and effective for use in self-therapy of the conditions discussed in this, and the next two lessons in this series.

Skin protectants are drugs that guard injured skin or mucous membranes against damage. They safeguard the skin from minor cuts, scrapes and abrasions, burns and sunburns; prevent and protect against chapped, cracked or wind-burned skin and lips; relieve minor irritation and itching of poison ivy, oak and sumac; and dry the oozing or weeping lesions of poison ivy, oak or sumac, and many other skin afflictions.

OTC drug products that contain skin protectants are intended to be applied only to external areas and must be kept out of the eyes. They should not be used on deep or puncture wounds, infected or lacerated skin except when indicated, and only as directed. They may be applied as frequently as necessary, but for periods generally not exceeding seven days unless on the direction and under the supervision of a physician.

The Itch Response

The warm temperatures of summer encourage outdoor activities. As individuals increase their exposure to poisonous plants, sunlight, and biting and stinging insects, they also increase their chance of acquiring a pruritic condition. Pruritus (itching) is the most common complaint of all dermatologic disorders. It is often difficult to treat pharmacologically. Itching can also signal the presence of severe, systemic pathology.

An itch is an irritating cutaneous sensation that evokes the impulse to scratch. Itching must be differentiated clinically from pruritus, although the terms are usually used interchangeably. *Itching* is a symptom. *Pruritus* refers to a condition causing generalized itching in the absence of a primary skin disorder.

There are numerous stimuli and noxious substances which mediate release of peripheral chemicals such as histamine, bradykinin, neurotensin, and substance P, which in turn incite itching. These secondary chemomediators act upon a complex network of nerve endings in the epidermis to incite the itch sensation.

Pain and itching share common stimuli and impulses traverse the same neuronal pathways. These non-myelinated C fibers are distributed throughout the upper regions of the dermis, mucous membranes, and cornea. Even with these similarities, there is still considerable doubt that itching is a modified form of pain even though this has been a long-held belief.

Several important points about itching are relevant to effective patient counseling on its control. The threshold for itching is lower at night, with increased skin temperature, and during periods of psychologic stress. Vasodilation, decreased cutaneous hydration, and a current or previous pruritic dermatosis enhance the itch response.

Itching is often relieved when the primary disorder is treated. This is not always possible. Examples include poison ivy/oak, and reactions following insect bites and stings. Once apparent, the conditions are not altered significantly with OTC therapy. Therefore, treatment of itching is actually the primary therapeutic goal.

Itching over large areas of the body that is generalized and persistent can suggest serious pathology. Specific systemic disorders include atopic diseases, chronic and obstructive renal failure, obstructive hepatic disease, diabetes mellitus, myxedema, gout, lymphoma and leukemia, and polycythemia vera. Pruritus that is not relieved by OTC antipruritic products, or persists beyond seven days, should be treated professionally since this may signal the presence of a serious disorder. Continuing to use a product without seeking professional assistance could delay appropriate treatment.

Treatment of Itching

The first response to itching invariably is scratching. Scratching an itch provides instantaneous, but transient relief. It can also lead to onset of the “itch-scratch cycle” with perpetuation of the unpleasant sensation. Relentless scratching and/or rubbing the area can also cause lichenification (skin thickening with smooth, shiny patches), urticarial papules (solid, red elevations), excoriation (shedding skin) and secondary infection.

Local Anesthetics. Local anesthetics interfere with the generation and transmission of nerve impulses. Benzocaine is often reported to cause sensitivity reactions in susceptible individuals. Most statements relating to the incidence of benzocaine-induced skin reactions are conflicting, and the incidence may be over-estimated. The North American Contact Dermatitis Group study showed that the incidence was five percent in patients with a history of skin disorders. In another study of 1,158 subjects, the incidence of reaction was only 0.17 percent. Patients who are sensitive to contact allergens such as from poison ivy/oak plants and are allergic to other chemicals, should use benzocaine cautiously, if at all.

Antihistamines. Antihistamines block the binding of histamine with its receptors and therefore help control itching. Many systemically administered antihistamines also help protect against non-histamine-induced itching because of their sedative effects.

Their mechanism of topical action is uncertain. It is presumed that at least part is due to blocking histamine receptors, presumably on the nerve endings. But this action cannot account for all therapeutic response. Antihistamines must bind with histamine receptors prior to histamine release to be maximally effective.

Topical application may impart almost immediate relief of itching. Moreover, there are numerous other chemomediators of itching besides histamine. Since topically applied antihistamines relieve itching, these lines of reasoning imply that a mechanism other than competitive blockade of histamine is responsible for relief of itching. Their benefit is most likely due to local anesthetic blockade of dermal sensory receptors.

Hydrocortisone. Switch of topical hydrocortisone products from prescription-only to OTC status was a significant breakthrough in the treatment of many dermatologic conditions including those which cause itching as a primary symptom. Neither topical hydrocortisone nor the stronger halogenated steroids reduce severe inflammation already formed. Used early in therapy, however, OTC products containing hydrocortisone will help reduce additional inflammation following the initial response.

Hydrocortisone has received widest recognition and the most extensive use in therapy of inflammatory dermatoses. It is the benchmark against which safety and effectiveness of new corticosteroids are measured. Tests that compare the relative potency of various corticosteroids traditionally rank hydrocortisone as a low-potency steroid when used for antiinflammatory effect. At the same time, hydrocortisone ranks high on safety. These facets make it ideal for self-administration.

Hydrocortisone constricts cutaneous blood vessels to prevent mobilization of polymorphonuclear leukocytes and monocytes into the area. It also antagonizes the inflammatory response of mast cells and others that release mediators of inflammation. Some authorities claim that vasoconstriction is not a consistent component of hydrocortisone's action and respond that they discern it in fewer than 10 percent of subjects tested.

OTC topical hydrocortisone products provide a safe and effective means for temporary relief of minor skin irritation including dermatitis. Nonetheless, several points need to be emphasized to maximize benefit and minimize the chance for adverse effects.

The patient should be advised to apply a thin film and massage it thoroughly into the skin, three to four times a day. Product labels warn against continued use for longer than seven days without physician supervision. If the condition does not clear by then, it may require specialist intervention. Moreover, the potential for systemic adverse effects following chronic self-therapy warrants this limitation.

Hydrocortisone products should not be used in children under two years of age. Young children are more susceptible to adverse effects should absorption occur through the skin. Absorption is increased with severely inflamed dermatitis, and infants have not yet fully developed complete dermal layers.

Cream dosage forms are commonly used because of favorable patient acceptance. They are non-greasy, rub in easily, and do not leave a residue. Creams are appropriate for nearly all approved indications and can be applied to any area of the body. Lotions are best for chafed areas, and for the scalp or other hairy areas because they spread easily. Ointments are preferred for dry, scaly lesions since they are emollient and retain moisture on the skin.

Patients should be advised to follow directions carefully and not exceed the recommended dosage. They should be made aware that antipruritic activity may require a day or two to onset. Topical use of hydrocortisone in OTC products is not associated with toxicity even on abraded skin when used as directed.

Increasing dermal humidity by use of an occlusive covering may enhance drug penetration 10-fold. Clothing and the vehicle may also occlude the skin and enhance absorption. However, unless instructed otherwise, the area should not be occluded.

Counterirritants. In low concentrations, counterirritants (camphor, menthol, phenol) depress the skin's pain/itch receptors by causing mild, localized irritation at other sites. Their exact antipruritic mechanism is not known. A portion of counterirritant therapy may be placebo, the user deriving benefit from the characteristic "medicinal" odors. Counterirritants are safe when used as directed, and may be relied on for antipruritic activity.

Wet Dressings. One of the often overlooked means to help control itching and reduce excessively dry skin which is causing the itching is with a wet dressing. In simplest form, the process involves soaking a piece of finely woven cloth or cotton in cold water, saline or sodium bicarbonate solution, wringing it slightly so as not to drip, then applying it to the skin. As the solution evaporates, it imparts a cooling (antipruritic) sensation. The cloth should not be more than a layer or two thick to maximize evaporation. It should be remoistened every 10 to 15 minutes and reapplied two to three

Table 2
Patient Information on the Correct Use of Products to Relieve Itching

- This product is for the temporary relief of itching associated with minor skin irritation.
- This product is for external use only. Do not use it near your eyes. If you accidentally swallow some of a liquid product, contact a doctor or poison control center right away.
- Follow the instructions listed on the label of this product.
- Do not use this product on children under two years of age, except on the advice and under the supervision of a doctor.
- If you are going to use an aerosol or pump spray product on your face, apply it on your hand or a piece of gauze or pledget of cotton before applying to your face.
- If itching is not relieved, if it persists longer than seven days or worsens, or if your skin becomes red, irritated, or inflamed while using this product, see a doctor for further advice.
- Keep this and all other medicines out of the reach of children.

For local anesthetics:

- Before you use a local anesthetic, check with your doctor or pharmacist if you have ever had any unusual or allergic reaction to this medicine or other local anesthetic, especially when applied to the skin or other areas of the body.
- Do not apply this product more often than three to four times a day, over extensive areas, or on raw, blistered or damaged skin.

Other helpful information:

- Keep your fingernails trimmed short, and edges filed smooth, to prevent damage from scratching. It is best to avoid excessive scratching.
- Do not wear rough or woolen clothing over an area that itches. Use a bed sheet between you and your bed covers.
- Try to avoid unnecessary tasks or situations that make you nervous or cause stress. These can worsen your itching.
- During the summer months, run your air conditioner on a low setting, or turn the compressor off occasionally, to keep your skin from becoming excessively dry.
- Following bathing, pat the area of your skin that itches, dry; do not rub it with a towel. Then, apply a thin layer of a moisturizing or protective skin care product. Your pharmacist can help you select an appropriate product.

times. The process should be repeated several times a day as needed.

For persistent itching or when vesiculation is especially severe, aluminum acetate (Burow's solution) in a 1:40 (2.5 percent) to 1:20 (5 percent) concentration is a safe and effective wetting agent. Domeboro tablets are a commercial formulation that, when dissolved in water, makes Burow's solution. Applied as instructed, it coagulates bacterial and serum protein, and is an effective antipruritic agent.

Wet dressings also have an additional benefit of causing gentle debridement and cleansing of the skin. The cloth must not be allowed to dry on the skin since it can adhere to it. When removed, it then increases the debriding action and causes greater skin damage with resultant exacerbated itching.

Auxiliary Measures. Itching is stimulated by a number of factors. Rough clothing, especially woolen, should not be worn over the affected area. Use of strong soaps or detergents should be minimized, especially those that are highly fragrant. Prolonged soaking in bath water should be avoided, and bath salts and bubble bath products should not be used. When emerging from a bath or shower, the individual should apply an occlusive skin protection product to the affected area. Fingernails should be kept trimmed short and edges filed smooth to prevent skin damage from scratching. Anxiety and stress should be avoided.

Brief cool baths constrict vessels and often soothe pruritus. Warm baths incite vasodilation and increase itching. This can nullify benefit from OTC products. Bathing is beneficial when itching occurs over an area too large to cover with a wet dressing. Soaking should not last longer than 10 to 20 minutes.

Counseling Patients

The best treatment for itching is to avoid contact with the offending cause. Persons who are at risk can begin antihistamine therapy a day or two in advance of the event (if they are not allergic to it). Alternatively, a liquid or chewable tablet form of an antihistamine, rather than solid dosage forms, should be used immediately after an insect bite or sting, or encounter with a poison ivy/oak plant. These will provide quick access of the drug to the blood and, hence, block histamine receptors more quickly than the other forms of the drug.

Patients should be strongly advised to limit scratching and rubbing their skin. More counseling information is provided in Table 2.

Continuing Education Quiz

This month`s questions are taken from the article on "Patient Counseling: Prevention and Treatment of Skin Injuries; Part 1: Basic Concepts and the Itch Response." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 7/15/00. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-97-008-H01.

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1. The outermost layer of skin is the:
   a. epidermis.
   b. corium.
   c. endodermis.
   d. dermis.

2. All of the following are safe and effective OTC skin protectants EXCEPT:
   a. cocoa butter.
   b. shark liver oil.
   c. colloidal oatmeal.
   d. sodium chloride.

3. Which of the following enhances the itch response?
   a. Decreased skin temperature
   b. Increased cutaneous hydration
   c. Psychologic stress
   d. Vasoconstriction

4. The mechanism of action of topically applied antihistamines in relieving itching is most likely:
   a. central nervous system blockade.
   b. local anesthetic blockade.
   c. prostaglandin inhibition.
   d. vasocontriction of subcutaneous blood vessels.

5. When counseling patients on the use of wet dressings to alleviate itching, it is important to relate the following.
   a. Leave dressing on for at least one hour.
   b. Cover the dressing with adhesive tape.
   c. Allow the dressing to dry on the skin.
   d. Use cold water, saline, or a sodium bicarbonate solution.

6. All of the following depress the skin's pain/itch receptors by causing mild localized irritation at other sites EXCEPT:
   a. menthol.
   b. benzocaine.
   c. camphor.
   d. phenol.

7. All of the following incite itching EXCEPT:
   a. bradykinin.
   b. histamine.
   c. norepinephrine.
   d. substance P.

8. All of the following are true statements about OTC topical hydrocortisone products EXCEPT:
   a. they can be used indefinitely without medical supervision as long as there are no signs of infection.
   b. ointments are preferred for dry, scaly lesions since they are emollient and retain moisture on the skin.
   c. their antipruritic activity may require a day or two before being noticed.
   d. they are safe and effective with no proof of systemic effects when used according to FDA-approved directions.

9. The stratum corneum consists mainly of:
   a. blood vessels.
   b. keratin.
   c. germinating cells.
   d. water.

10. The regenerative layer of skin is the stratum:
   a. corneum.
   b. lucidum.
   c. germinativum.
   d. granulosum.

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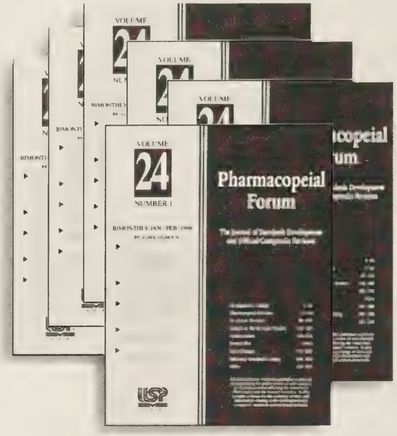

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Americans "At Risk" Through Self-Medication

According to a National Survey by APhA and *Prevention* Magazine

Americans' self-reliance when it comes to treating everyday health problems may lead to the misuse of common, over-the-counter medications (OTCs). As many as eight in ten of the nation's adults treat themselves before calling on a health-care professional when suffering from common ills like headaches (80%), upset stomachs (76%), coughs/colds (73%), and fevers (71%), according to a new national survey of 1,202 adults conducted for *Prevention* magazine and the American Pharmaceutical Association (APhA).

While a little self-reliance might be a good thing, a third of all adults (33%) admit that they have taken more than the recommended dose of an OTC product because they felt they needed to in order to effectively treat their condition -- and, over a third (35%) think it is likely that their self-treatment with an OTC could hide symptoms of a more serious problem requiring a doctor's attention. "Consumers clearly want access to OTCs to treat a wide range of conditions," said Lucinda L. Maine, APhA's Senior Vice President for Professional Affairs. "By their own admission, they may not always use them appropriately, and this can have serious health consequences. The growing availability of non-prescription products means that now more than ever, the consumer needs advice from capable health professionals - particularly pharmacists."

The survey, *Navigating the Medication Marketplace: How Consumers Choose*, suggests that when Americans actively seek information about how to choose and use medications, they rely upon three basic sources for OTC products: the product label (80%), physicians (75%), and pharmacists (70%).

However, despite their reliance on the label, as many as three in ten consumers don't think it is very understandable when it comes to vital information like the symptoms the product is supposed to treat (33%), side-effects of the medication (35%), or warnings about taking other medications simultaneously (36%). "What the survey really shows is that consumers want to take care of themselves safely, and they will read the fine print and seek key people for help," says Ed Slaughter, Research Director at *Prevention*. "That's where good labeling information and a patient pharmacist really come in handy!"

In fact, consumers trust their pharmacist so much that more than half (58%) think of that person in the same way they think of their regular doctor - as someone they can talk to about their medication needs. Two-thirds (64%) of consumers who have a "personal" pharmacist say they always or sometimes talk to him or her when selecting OTC medications.

Furthermore, consumers trust and act on this advice. Because of a pharmacist's recommendation, more than half (57%) began using a specific OTC product and more than one-third (39%) decided not to purchase one specifically because of this advice.

Other survey findings show that consumers talk to their pharmacists and physicians about prescription medications, too. Nearly nine out of 10 consumers say their doctor or pharmacist has talked to them about potential side-effect (92%), the availability of generic equivalents (85%), and possible interactions with other prescription medications (89%). Eighty-seven percent say their pharmacist or physician told them about possible interactions with OTC medications.

Note: Full survey results are available from Sarah Jane Smedley, *Prevention* at 610-967-8783 or Jeanette L. Jurkiewicz, APhA at 202-429-7537.

A Look Back to 1968

This letter was published in the Maryland Pharmacist—
Volume XLIII - No. 7 April, 1968

1968 Convention Programs

All pharmacists and our allied colleagues are urged to complete their plans to attend the 86th Annual Convention of the MPA, July 8-11 at the Shelburne Hotel, Atlantic City, New Jersey.

A cocktail party will welcome early arrivals Sunday evening July 7. The business session will begin Monday afternoon July 8th. A special program for the ladies will be held at 3:00 p.m. Monday featuring Reese Palley with a demonstration on the subject of his world famous bird ceramic sculpture.

Tuesday, Wednesday and Thursday mornings will feature programs vital to all in pharmacy, whether community, hospital distribution or manufacturing. Speakers include: Joseph A. Oddis, Executive Secretary, American Society of Hospital Pharmacists; Morris E. Blatman, Executive Secretary, Philadelphia Association Retail Druggists; Dr. William J. Kinnard, Jr. incoming Dean, University of Maryland School of Pharmacy; Donald E. Baker, Pharmacy Consultant, Regional Office, Department of Health, Education and Welfare; Noel Parris, Chief Pharmacist, Columbia Point OEO Comprehensive Health Center, Boston; William L. Ford, Executive Vice President, National Wholesale Druggists Association; and others. A program of "table clinics" will again be held featuring practicing pharmacists who will discuss "what works for them."

Entertainment will include special programs for the ladies and youngsters at the hotel and at the swimming pool. Monday night features admission to the new Smithville Music Fair. TAMPA will go all out Tuesday evening with a Carnival Deluxe and prizes galore. A Broadway show will be presented Wednesday evening followed by the President's Cocktail Party by Young Drug Products. Thursday evening will feature the Banquet preceded by the drug wholesalers cocktail party.

This is just a capsule view of a most entertaining as well as informative program.

Be a participating member of your profession. Attend and have a hand in formulating policies and decisions for the future.

Sincerely,

Nathan I. Gruz
Executive Secretary

Don't forget to register for the
1998 MPhA Convention, June 13-16, 1998
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↞ *Details on Page 9*

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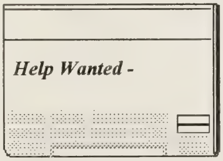

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MARYLAND

Pharmacist

Volume 74, No. 3

President's Commentary

Patient Care! Pharmacist Care!

H.R. 1525

The "Lowey Bill"

Pepsi-Cola

Born in N.C. Pharmacy

Pharmacy and the Law

When Bad Things Happen
--Be Prepared

Continuing Education

"Patient Counseling: Prevention and Treatment of Skin Injuries; Part 2: Poison Ivy, Prickly Heat, and Diaper Dermatitis"

Gerard A. Herpel, P.D.
MPhA's 1998-1999 President

MARYLAND PHARMACISTS ASSOCIATION

July / August / September 1998

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The Official Publication of the Maryland Pharmacists Association

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President's Commentary
Patient Care! Pharmacist Care!

Gerard A. Herpel, P.D.

I look on with anticipation, as I embark on my year as President. This could be one of the most exciting times for both the Maryland Pharmacists Association and The Profession of Pharmacy.

I have seen plenty of change since I was a young know-it-all coming out of Pharmacy School. Well, I don't know-it-all since I can't remember it all; but, I do know that change is upon us! The pharmacists who recognize these changes are the lucky ones who will thrive in the future. It is the Pharmacist who makes house calls to care for a diabetic patient; the Pharmacist who compounds a hospice patient's pain meds into a troche; and the Pharmacist who helps an asthma patient decrease his number of attacks by better compliance.

We are part of the most respected profession in the land. It is time we take our profession into our own hands and take control of our own destiny. We must do this together. The strides we have accomplished recently with the rewriting of The Pharmacy Practice Act was only the beginning. The passing of the Collaborative Practice Act in Annapolis in 1999 is essential to our future! It is MPhA who the legislators and the communities in our state seek when they have questions or need answers concerning our profession. For this reason, I want MPhA to be the leader in this fight.

I know I would only be preaching to the choir, if I was to rattle off all the different ways that we produce better outcomes for the patients that are under our care. However, we must be the ones who toot our own horns. *We must come out in numbers to make sure that Annapolis hears our voice!*

Is our profession as full of apathy as it appears? Why is it, that less than 20% of the pharmacists in our state feels that there is a need to belong to MPhA? Does the other 80% not care? Do they not want a say in how their profession and livelihood evolves and changes around them?

Our Association needs to grow. We need to make our voice as strong as possible. The more members we have--the stronger we will be. I am asking each member to talk to other pharmacists about our association. Explain that we need to join together, so *Pharmacists are making the decision that effect Pharmacists.*

If every member can bring in one member this year, we can keep our state association on solid footing. This will give us the numbers that makes a strong voice which commands respect throughout the state.

I was talking to a pharmacist from Damascus who informed me that she was a silent member of the association. Well, she is just as important as the Trustees, Committee Members, and the Volunteers who are doing the work that needs to be done. Every pharmacist who is a member supports us in our endeavors, by adding to our size and ultimate voice.

I want to make the Maryland Pharmacists Association the "*Voice of Pharmacy*," in the State of Maryland. Whether, we practice in a community setting, health system, hospital, consulting, long term care, or managed care; we all share one common bond--our profession.

These are exciting times! Plenty can and will happen in the coming year. And how it turns out is entirely up to us. Remember, every member is important to MPhA and a stronger association is important to our members. Be proud that we belong to the most respected profession in the land!

Director's Column

Howard R. Schiff, P.D.
Executive Director

Introduction

At this writing it is the end of August, this magazine has to go to the printer, and I start as Executive Director on September 1. I am excited and enthused and a little bit apprehensive. I have been a community pharmacist for more than 40 years and have worked in both independent and chain settings. I was a store owner for 30 of those years. Going from behind the counter to behind a desk for the first time in my life will give me a whole new perspective on the practice of pharmacy. This is true even though I am a Past President and have served on the Board of Trustees and in other capacities for this organization. I welcome the challenges ahead and will do my best to represent the professional interest of pharmacists in the State of Maryland.

The following was prepared by outgoing executive director, Robert Boerner

We will be moving from E. F. Kelly Building at 650 West Lombard Street, to interim quarters at 29 South Greene Street and by the late summer or early fall of 1999, to a new facility at the corner of Saratoga and Pine Streets adjacent to the UMAB campus security force. The new building will house MPhA, the School of Pharmacy and the Maryland Poison Center. The final design of the interior space is still under review, but current plans call for office space, space for continuing education classes and space for display of some of the museum artifacts presently located in the Kelly Building.

George Griffenhagen, formerly of the American Pharmaceutical Association, and an acknowledged expert in the field of pharmacy-related artifacts recently reviewed our museum collection and archives. He has made useful recommendations regarding the preservation of these collections. With his report on the museum and archives, he provided a brief insight into the relationship of the MPhA, the School of Pharmacy and the APhA which, with his permission, I have summarized here.

The Maryland College of Pharmacy is the second oldest school of pharmacy in the U. S. that is still operating. It was founded in 1840 and became a part of the state university in 1920. The Maryland College of Pharmacy helped organize the Maryland Pharmaceutical Association (now Maryland Pharmacists Association) and hosted its first meeting on October 5, 1882.

In 1953 the Maryland Pharmacists Association completed construction of a colonial brick building on the university campus adjacent to the School of Pharmacy which was then housed in Dunning Hall. Dunning Hall was named after Henry A. B. Dunning who was a Maryland College of Pharmacy graduate in 1897 and President of the Maryland Pharmaceutical Association during 1926-27. The association building was named after Evander F. Kelly, Dean of the Maryland College of Pharmacy and APhA Secretary during the time the APhA headquarters was located at the Maryland Pharmaceutical Association building.

There was time for reflection on the events that have brought us to this point of departure. The era of the Kelly Building is ending and the era of a new building is about to begin.

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Support Is Mounting...

because pharmacists are talking to their customers and asking them to sign petitions protesting mail order abuses, patients throughout the nation are quickly learning why they should support the prescription drug benefit equity act.

By Andy Giegerich

Some people believe that the states of New York and California set the trends for the rest of the nation. When it comes to H.R. 1525, the Prescription Drug Benefit Equity Act, those people are right. The bill from New York Congresswoman Nit Lowey, which would level the playing field between community and mail order pharmacies, is enjoying strong support among patients nationwide, with particularly vigorous activity in California.

One indicator of how popular a cause H.R. 1525—called the "Lowey Bill" after sponsor Lowey (D-N.Y.)—has become is the recent drive initiated by the California Pharmacists Association. The group has sent out to pharmacists more than 1,000 copies of the NCPA petition in support of the Lowey bill. With these and petitions from other states now flowing into NCPA headquarters in Alexandria, Virginia, NCPA has gathered more than 5,000 signatures—and counting—in support of the Lowey bill.

The upshot is that patients are supporting a national legislative effort that ranks among the most important ever for community pharmacists.

"As you are aware, many health plans and health insurance groups force consumers to order their drugs by mail, thereby foregoing the valuable services of their local pharmacists," wrote CPhA Government Affairs Manager Jennifer Gramlich in a memo to state pharmacists. "The Lowey bill seeks to eliminate this inequity by prohibiting health insurers and plans from offering the consumer only mail order prescriptions. The bill specifies that as long as the local pharmacy meets the health plan's benefit and cost-sharing requirements, the consumer is free to choose community pharmacy services over mail order."

Gramlich further urged California pharmacists to explain to patients how face-to-face pharmacists care services—such as monitoring treatment, watching for drug interactions, and counseling—benefits them. "All these benefits are lost in the mail order process," Gramlich noted.

One California pharmacist who agrees with Gramlich is NCPA Secretary-Treasurer John Tilley, owner of Zweber Apothecary in Downey. "This is truly one of the best bills we've seen in years," says Tilley. "It's always a pleasure to talk to patients who want to know more about the petition. The thing is, no one has refused to sign it. Given the choice, patients will always choose face-to-face, locally based service over mail order."

Backed by the Nation

The Washington State pharmacists attending NCPA's legislative conference in March successfully lobbied Rep. George Nethercutt (R.Wash.) to sign on as a bill cosponsor. Washington State Pharmacists Association President Linda Garrelts, of Spokane, wrote an editorial in the state's monthly magazine strongly backing the measure. "This is absolutely vital for community pharmacy," wrote Garrelts. "Simply stated, this bill would mean that drug benefit design would provide for equal co-pays and equal days supply for prescriptions, no matter where the prescription was provided—mail order or community pharmacy."

Garrelts added that the bill is not really anti-mail order; "The bill would allow patients a choice between mail order and community pharmacy; the patient could [then] choose the type of pharmacy which suits his or her circumstances best. If this bill passes, the financial barrier [that] prohibits many patients from accessing community pharmacy would be removed."

In Florida, Dave Adams, owner of Adams Pharmacy in Lynn Haven, has collected several hundred signatures on NCPA's petition from patients who are fed up with their lack of a realistic pharmacy option. A perfect illustration of the mail order problem occurred on June 10 when a patient came into Adams Pharmacy and asked for a small supply of a blood pressure medication.

"He was very upset because he had sent out for a 90-day supply on June 1 from a mail order company, and it hadn't arrived," says Adams. "I had to sell him just a few days' supply because he was going out of town on the 11th." The man, after railing against the mail order pharmacy for several minutes, enthusiastically signed Adams' petition.

Adams says the NCPA petitions (see the petition on page 13) generate a lot of discussion among his patients. "Patients are very excited when they see that there's a bill that would give them the freedom to choose their own pharmacy," he says. "They're a bit angry that they get steered to a mail order pharmacy, where they pay $15 for a three-month supply, and have to pay $15 for a month's supply from me. They're also fed up with HMOs [health maintenance organizations] telling them what doctors they can see or what drugs those doctors can prescribe."

"If the Lowey bill passes, then they'll have the opportunity to come to us whenever they can and keep their money in our community."

Adams has convinced his city's Chamber of Commerce to back the bill: The group sent a letter supporting the Lowey measure to Rep. Allen Boyd (D-Fla.). "I think that will help us out here tremendously" in getting Boyd to cosponsor the bill, says Adams.

Paralleling Adams' experience in his community, strong pockets of patient support for Lowey continue to show up in New York, where Pharmacist-Owned Pharmacies (POPS), a 143-pharmacy collective just north of New York City, continues to collect a multitude of signatures on pro-Lowey petitions. POPS has kept up a Lowey bill marketing campaign that includes newspaper ads and radio commercials along with the petitions. POPS has already forwarded its petitions to congressional offices.

"It's clear that patients in New York want this to pass," says Jack Nicolais, owner of Saxon Chemists in White Plains, New York, and president of POPS. "They're tired of not having a say in where they get their prescriptions."

Oklahoma pharmacists have also utilized the NCPA petition to their advantage, collecting more than 3,000 signatures so far. The group has met with several state association representatives on the Lowey bill, discussing the measure's importance to pharmacy's competitive balance.

How is the Lowey bill important to maintaining a competitive balance in pharmacy? Here's a refresher course:

- The Lowey bill would level the pharmacy playing field by prohibiting group health plans and health insurers from providing mail order prescription drug coverage without also providing non-mail order prescription drug coverage, as long as pharmacies meet the plans' benefit and cost-sharing requirements. It would further ban monetary payments or rebates to encourage providers to accept less than the minimum protections available under this act.

- Lowey introduced the bill after meeting with members of POPS in New York. Lowey, in one of several sessions with POPS, told the pharmacists she had received several complaints from constituents—a mix of federal employees and local clergy—who were financially coerced by their health plans to use mail order pharmacies.

- The Lowey bill removes mail order's unfair, unwarranted, and non-competitive cost advantage. Giving patients a choice uninfluenced by cost will allow independent pharmacists to demonstrate their obvious service advantages over mail order, such as convenience and face-to-face counseling. The bill would also require Medicaid and Medicare to direct health plans to follow the Lowey provisions, which would further apply the rules to health benefits purchased for federal employees. Currently, the Federal Employee Health Benefits Plan levies no charge on federal employees for mail order prescriptions but charges a 20 percent copayment for medications purchased at neighborhood pharmacies.

As patients are becoming demonstrably more supportive of H.R. 1525, legislators are joining them. The bill now has 24 cosponsors in addition to Lowey, with several joining the fold after NCPA's legislative conference (see accompanying list of cosponsors).

"Our members did a great job of lobbying [for the Lowey bill] during their Capitol Hill visits," says NCPA Senior Vice President for Government Affairs John Rector. "Since then, I've talked to several representatives who want to know more about the bill, as well as to several who have since become cosponsors."

NCPA is urging community pharmacists whose representatives have not signed on to cosponsor the Lowey bill to make a call or write a few letters. "Contact your representative—particularly if they are Republican—and urge them to cosponsor the bill for the sake of independent pharmacy and, more importantly, for the sake of patients," Rector advises. "We've got to keep the pressure on."

Lowey, speaking at NCPA's legislative conference, said as much during her 45-minute address, challenging Georgia pharmacists to get the endorsement of House Speaker Newt Gingrich. Before Lowey's speech, Gingrich told community pharmacists that the impersonal nature of mail order pharmacy is "the wave of the past."

Said Lowey, "You've played such an important role in our communities for as long as I can remember. You're a trusted figure, the whole family knows you, and keeping you there is vital to our safe, strong communities...The relationship between you and your communities is important.

"My bill is all about having a level playing field so you can compete with large mail order firms. That's all anyone can ask."

Lowey struck many of the same themes when introducing the bill last year. "Hard-working Americans should not be forced to entrust their health to pharmacists working at a firm thousands of miles away. They deserve the right to continue seeing the neighborhood pharmacists they've grown to trust," she said in April 1997. "While most plans do not require beneficiaries to purchase medication through the mail, a growing number of plans are now charging consumers substantially more for the privilege of using their neighborhood pharmacist. That includes the Federal Employee Health Benefits Plan, which charges Federal employees nothing for mail order prescriptions, but a 20 percent copayment for medications purchased through their neighborhood pharmacist.

"In an era when health care costs are eating away at the earnings and savings of too many Americans, especially our seniors, forcing them to pay significantly more to use their trusted pharmacist really means no choice at all. My bill will eliminate this cost discrepancy and give Americans a real choice."

The Perfect Solution

The Lowey bill essentially would ban health plans from coercing patients to use mail order pharmacies. It would give consumers a reasonable choice between retail and mail order pharmacies, allowing, once and for all, independent pharmacists to demonstrate their superiority over mail order pharmacies in service, convenience, positive patient outcomes, and even price.

The objective of the bill is one that every community pharmacist should support, and should get their customers to support. To show that support, you may copy the petition on page 13 and collect patient signatures. The wording on the petition says it all:

"I support such federal legislation to eliminate discrimination against those of us who want to continue receiving services from our local community pharmacist. There is nothing more precious than peace of mind and good health."

Nita Lowey

Background Check

To community pharmacists, the name "Nita Lowey" conjures an image of a modern champion of fairness and advocate of consumers' rights.

But Lowey, the Democrat who represents New York's 18th District, stands for much more than the Prescription Drug Benefit Equity Act. During her six terms in Congress, she has become known as a passionate supporter of reducing federal waste who takes a tough stance on crime.

Lowey is a member of the House Appropriations Committee, from which she emerged as the committee's leading advocate of breast cancer research, women's health, preventive health programs, worker retraining initiatives, and education reform.

Lowey also sits on the Labor, Health and Human Services, and Education Appropriations Subcommittee, which funds federal health research, education, and worker safety and retraining programs. She is also a member of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, which has jurisdiction over nutrition and environmental protection programs.

As she builds her reputation as a proconsumer health care defender, Lowey also has an interest in eliminating unnecessary and wasteful programs and reducing the federal deficit. Among legislators, she is known for a bill that passed during the 102nd Congress that will save several billion dollars each year by reducing student loan default rates. She has also authored legislation to expand federal support for improvements in our nation's waste-water treatment plants.

In March, Lowey won accolades for introducing a bill to establish a national "driving-while-impaired" standard of 0.08 Blood Alcohol Content (BAC), below the 0.10 BAC limit common to most states. The bill was subsequently introduced in the Senate and passed by a 62 to 32 vote. Lowey also introduced "The Deadly Driver Reduction and Burton H. Greene Memorial Act," which would penalize states that fail to impose mandatory minimum penalties for drunk drivers who are repeat offenders. Lowey has also earned kudos for sponsoring a welfare reform bill that will encourage work, job training, and personal responsibility.

A graduate of the Bronx High School of Science in New York and Mt. Holyoke College, Lowey is married to Stephen Lowey. She has three children.

THE PRO-CONSUMER

HONOR ROLL

As of mid-June, the following representatives have signed on as cosponsors to H.R. 1525, the Prescription Drug Benefit Equity Act:

Rep. Bernard Sanders (I-Ver.)
Rep. Michael McNulty (D-N.Y.)
Rep. Charles Rangel (D-Mich.)
Rep. Stephen Horn (R-N.Y.)
Rep. Martin Frost (D-Texas)
Rep. Sherrod Brown (D-Ohio)
Rep. Gary Ackerman (D-N.Y.)
Rep. Gene Green (D-Texas)
Rep. Peter DeFazio (D-Oreg.)
Rep. Robert Andrews (D-N.J.)
Rep. Shelia Jackson-Lee (D-Texas)
Rep. James Clyburn (D-S.C.)
Rep. James Maloney (D-N.Y.)
Rep. Greg Ganske (R-Iowa)
Rep. Earl Hilliard (D-Ala.)
Rep. George Nethercutt (R-Wash.)
Rep. Ciro Rodriguez (D-Texas)
Rep. Patsy Mink (D-Hawaii)
Rep. Carolyn McCarthy (D-N.Y.)
Rep. Frank LoBiondo (R-N.J.)
Rep. Matthew Martinez (D-Calif.)
Rep. James Traficant (D-Ohio)
Rep. Constance Morella (R-Md.)
Rep. George Brown (D-Calif.)

If your representative is not a cosponsor, call him or her today at the U.S. Capitol at 202-224-3121. Pharmacists should tell their representatives that constituents' health care is at stake.

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America's Pharmacist • July 1998

Policies of the Maryland Pharmacists Association

Through the House of Delegates process, MPhA's objectives and goals are developed. These policies were adopted by resolution.

Freedom of Choice of Pharmacy
Adopted June 1996
The Maryland Pharmacists Association will pursue action to insure patient freedom of choice without any monetary penalty.

Mail Order
Adopted June 1986
The Maryland Pharmacists Association will continue its efforts to obtain regulation for the protection of the public health for out-of-state mail order prescription drug programs.

The MPhA will continue its efforts to educate the public on the disadvantages of mail order prescription drug programs and the benefits of contemporary community pharmacy practice.

Adopted June 1984
The Maryland Pharmacists Association condemns the practice of mail order prescription drug services as being unprofessional.

The MPhA shall develop a public education program to alert consumers to the advantages of community pharmacy practice and the hazards of mail order prescription drug services.

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PETITION

To the U.S. Senate and the U.S. House of Representatives

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ACCESS

WHEREAS It is bad medicine for Americans that health policies discourage the use of a local pharmacist or even eliminate the choice altogether.

WHEREAS Americans trust their local pharmacist and rely on their pharmacist to help ensure that a prescribed drug not only is right for them, but that they can obtain the product without the fear that it will be damaged, delayed, or lost in the mail.

WHEREAS Hardworking Americans should not be forced to entrust their health to mail order companies thousands of miles away and deserve the right to continue seeing the local pharmacists they have grown to trust.

WHEREAS The Prescription Drug Benefit Equity Act, H.R.1525, (by Representative Nita Lowey) would require equivalent benefits, i.e., co-pay or deductibles, for mail order and for the local pharmacist.

THEREFORE I support such federal legislation to eliminate discrimination against those of us who want to continue receiving services from our local community pharmacist. There is nothing more precious than peace of mind and good health.

Signed: Date:
Address:
Congressional District:

Signed: Date:
Address:
Congressional District:

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Pepsi-Cola: Born in N.C. Pharmacy

The story of Pepsi began at the turn of the century when the drugstore soda fountain was one of the most popular places for people to gather at day's end to catch up on the news and enjoy a refreshing drink. In 1898, small town pharmacist Caleb Bradham of New Bern, N.C., experimented with various mixtures of coca leaf and kola nut — thought to have extraordinary health benefits — in making a fountain drink that was delicious, aided in digestion and boosted energy. His blend of syrup, spices and soda water affectionately dubbed "Brad's Drink" by his customers. Bradham later renamed it Pepsi-Cola, launching what soon became a national favorite.

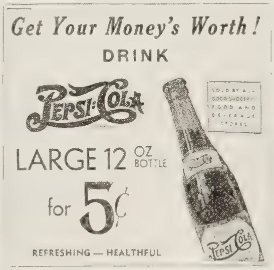
Caleb Bradham, inventor of Pepsi-Cola

Bradham, born in Chinquapin, N.C., attended the University of North Carolina for three years before heading to medical school at the University of Maryland. After completing his second year of medical school, his father's business failed, and Bradham was forced to move home in 1891. But two years later, a local drugstore in New Bern came up for sale, and this medical student-turned school teacher managed to purchase the store almost entirely on credit. By July 9, 1895, he was registered with the North Carolina Board of Pharmacy. However, it was his skill for mixing drinks, not drugs, that made him famous. The soft drink industry took off when a few of the "cola" drinks concocted in pharmacies around the country became so popular that their recipes were patented and trademarked for mass distribution to other drugstores. To market his new beverage, Bradham formed the Pepsi-Cola Company in the back room of his pharmacy in 1902, selling exclusively to soda fountains. The new drink's quick popularity convinced Bradham to apply for a patent and bottle Pepsi-Cola so that people could enjoy it anywhere.

By June 1903, "Pepsi-Cola" was officially registered with the U.S. Patent Office, and business boomed. Sales leapt from 19,848 gallons in 1904 to 104,029 gallons by 1907. By the end of 1910, Bradham had established Pepsi-Cola franchises in 24 states, embodying more than 280 bottlers. This strong franchise system provided a solid foundation on which Bradham pioneered an immense corporation.

The Pepsi-Cola Company enjoyed nearly 20 years of success before experiencing a setback during the sugar crisis of World War I. The price of sugar fluctuated between high and low extremes, and the cost of doing business increased dramatically for Bradham. By 1921 only two plants remained open, and in 1923 Bradham declared bankruptcy, placing his beloved Pepsi trademark up for sale.

Ownership of the Pepsi-Cola Company changed hands several times throughout the 1920s, and the company experienced its second bankruptcy before Charles G. Guth appeared on the scene to secure the soft drink's future. A successful businessman in the height of the Great Depression, Guth aimed to reinvigorate the aching company by aiming directly for the customer. He sold 12-ounce bottles of Pepsi for a nickel each, beating his competitor's standard offering a six-ounce drink for the same price. Touting Pepsi-Cola as "Twice as much for a nickel,"



Pepsi newspaper ad promoting the first 12-ounce soft drink for a nickel

Guth expanded the idea throughout the Pepsi-Cola system, resulting in great success.

Pepsi experienced an era of international growth in the 1930s as the company established franchises in Canada and registered its trademark in Latin America and the Soviet Union. Company ownership again changed hands, and new leadership employed keen strategy to prevent the sugar shortage of World War II from adversely impacting the rising company. Pepsi-Cola surged to the forefront of the national war effort, adopting a new patriotic bottle label and opening a USO Canteen in New York City where more than a million families recorded messages for their loved ones serving overseas.

Vigorous ad campaigns characterized Pepsi's phenomenal post-war growth, and by 1976, Pepsi-Cola became the single largest-selling soft drink brand in American supermarkets. At the dawn of the 1980s, Pepsi was the top brand in take home sales. The famous soft drink had traveled into outer space on a shuttle and the company crossed another new frontier in the 1980s by beginning distribution in China. By the end of the decade, more than 600 Pepsi-Cola plants were operating in 148 countries and territories throughout the world.

From New Year's Day through May of this year, Pepsi-Cola has celebrated *100 Years of Pepsi* with events across the Carolinas, including a celebration weekend in New Bern, the birthplace of the drink. The original Bradham pharmacy was restored for the event, and a statue in his honor was dedicated in the Sheraton Courtyard.

Today, Pepsi-Cola spans the globe with profits surpassing $1 billion, but Caleb Bradham's unique concoction is still the pride of the Carolinas.

A Look Back to 1953

This Editorial was published in the Maryland Pharmacist
Volume XXVIII - No. 5 February, 1953

Kelly Memorial Dedication

...and so it came to pass. On Friday, January, sixteenth, nineteen hundred and fifty-three, after years of dreaming and planning, the Kelly Memorial Building was dedicated.

Approximately five hundred men and women representing all phases of the health professions—Medicine, Dentistry, Nursing, Pharmacy— gathered to pay tribute to Dr. Kelly, who had contributed so much to the advancement of Pharmacy during his lifetime.

The assemblage included Theodore R. McKeldin, Governor of Maryland, Thomas D'Alesandro, Jr., Mayor of Baltimore, Dr. H. C. Byrd, President, University of Maryland, members of the University Board of Regents, Deans of the Schools of the University, and many other state and city officials and dignitaries. Also present were members of the American Pharmaceutical Association Council, Trustees of the United States Pharmacopoeial Convention, members of the Drug Trade Conference, the American Foundation for Pharmaceutical Education, including secretaries and other officers and many members of our profession from other states and the District of Columbia, Representatives of the various branches of our armed forces and the public health service also attended the dedication.

The Pharmacists of Maryland feel justly proud of the Kelly Memorial Building firstly, because it memorializes a leader in Pharmacy, who although not a native son, had spent the best years of his life in Maryland, and during this time had endeared himself to all who were fortunate enough to know him; secondly, because it gives us a "home" to work in and from—to carry on the increasing responsibility that Pharmacy has assumed in the community.

The Kelly Memorial Building should serve as an inspiration to Pharmacists in every state of the union and Maryland hopes that other states will follow suit. Although not an easy task, it can be done, and after the anxiety, sweat, and toil has been expended; the exhilarating knowledge of achievement and the prestige and dignity accomplished is worth the effort.

To all those that contributed to the success of the Kelly Memorial and its dedication, the Pharmacists of Maryland offer their profound appreciation.

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Counseling Notes for Pharmacists

Balancing the Bipolar See-Saw

Most patients are young when they first experience an episode of bipolar disorder, or manic-depressive illness. The average age of onset is the mid-20s. More than 2.5 million Americans have this devastating mental illness, with men and women affected in about equal numbers. Because bipolar disorder is virtually always recurrent, it is a lifetime condition. So it behooves patients and family members to become experts—learning everything there is to know about the condition and treatments is the best way to accept and manage the disease. Pharmacists can play a significant role here, if they choose to.

First, it is essential for patients and their families to understand that, like other major mental illnesses, bipolar disorder results from a chemical imbalance, *not* a personality disorder or bad family dynamics.

Mood swings are normal—everybody has them. But the bipolar patient manifests huge extremes, from a euphoric, aggressive high to a low that can render the person catatonic and even suicidal. An early sign of manic-depressive illness may be hypomania—a state in which the patient shows excessive energy, moodiness and irritability, and impulsive or reckless behaviors. Initially, the person feels good about this energy and fails to recognize that anything is wrong. Untreated, the disease gets worse and generally leads to full-fledged mania and depression, although some patients may experience repeated depression and only an occasional episode of hypomania (bipolar II disorder).

Signs and symptoms of mania are: increased energy and activity; racing thoughts and rapid talking; excessive euphoria; irritability and distractibility; decreased need to sleep; illusions of grandeur; radically increased sexual drive; uncharacteristically aggressive behavior and poor judgement; and denying that anything is wrong.

As with major depression, the lows of bipolar disorder include: persistent sadness; feeling empty and/or anxious; feeling guilty, worthless, hopeless and helpless; loss of interest or pleasure in normal activities, including sex; feeling tired or slowed down; sleep disturbances; weight loss or gain; thoughts of death or suicide; and suicide attempts.

Episodes can last days, months, possibly even years. Without treatment, manic or hypomanic episodes generally last a few months, while the depressive episodes can last more than six months. Some patients recover completely between episodes, while other never quite regain normal mood stability. Moreover, if the condition is allowed to run its course without treatment, the chances of more frequent, more severe and more prolonged relapses are greater.

Patients need to know that treatment is available. Encourage them to seek psychopharmacologic and psychotherapeutic help. Both acute and preventive medications are available for bipolar disorder, and most patients need them both. Added to medications, psychotherapy helps people handle stress, solve problems and work out relationship issues inside and outside the family. Most important, *knowledge* will empower a patient to monitor and recognize early warning signs of exacerbation and seek appropriate treatment, possibly preventing a full-blown manic or depressive episode.

For additional resources to help educate your patients, contact the *National Institutes of Mental Health (NIMH)* at 800-421-4211 or *The National Alliance for the Mentally Ill (NAMI)* at 703-524-7600.

Send Inquiries to: Pharm/alert, c/o Health Care Marketing Services, Inc., PO Box AP, Los Altos, CA 94023 650-941-955 • FAX 650-941-2082

Pharm/alert® Notes

Health Tips for Patients

Mood Swing

Bipolar disorder, also known as manic-depressive illness, is a mental illness that involves extreme mood swings. A person will go from feeling very "high" and irritable or excitable, to feeling profoundly sad and hopeless—with periods of quite normal moods in between.

- More than 2.5 million (1-1.5%) Americans have bipolar disorder, which often runs in families.

- Extreme highs begin as a pleasurable sense of increased energy and creativity, and euphoria or irritability—but they quickly go out of control to become a full-blown manic episode. Other symptoms are:

  - having an abundance of energy with little sleep
  - having racing thoughts and talking so fast that others can't follow you
  - being too easily distracted
  - having an inflated feeling of power and self-importance
  - doing reckless things with no thought of the consequences

- Depressive symptoms last at least two weeks and include feeling extremely sad and losing interest in things you normally enjoy. Other symptoms of depression include:

  - feeling worthless, guilty or hopeless
  - sleep and appetite disturbances
  - problems concentrating or making decisions
  - having very little energy, feeling tired all the time
  - feeling slowed down, or too agitated to sit still
  - thoughts of suicide or death

Please call your physician if you have these symptoms, especially if they persist. The symptoms may result from a chemical imbalance and are not your fault. Effective treatment is available to help relieve the suffering of bipolar disorder.

For more information about bipolar disorder
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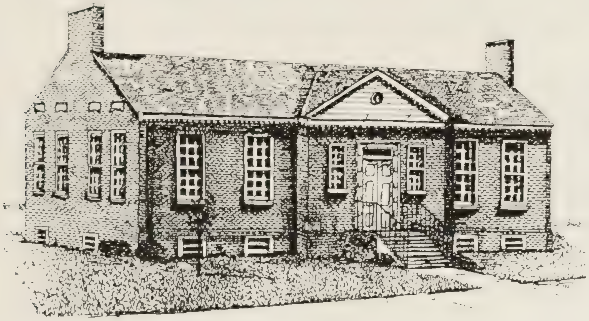
Kelly Building Illustrates Closeness Between School and Association

David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy



Named after a prominent dean of the Maryland School of Pharmacy and located on prime real estate in the heart of the University of Maryland campus in downtown Baltimore, the Evander F. Kelly Memorial Building has served as the headquarters for the Maryland Pharmacists Association since 1954. Built with funds raised by MPhA members on land provided by the University's Board of Regents, the building is unique in American pharmacy in its illustration of cooperation and goodwill between Maryland's pharmacists and the state's only school of pharmacy, one of the oldest in the nation. Over the years the relationship between the two organizations has been close and productive. Many MPhA members are also members of the School's preceptor faculty, while others serve on advisory boards and committees as well as assisting with recruiting and interviewing potential students. Faculty have advised the Association on scientific and professional issues, plan and deliver continuing education offerings, and have held office. The Dean of the School is an ex officio member of MPhA's Board of Trustees. Most recently the Association and the School have joined with other Maryland pharmacy organizations to overhaul the state's Pharmacy Practice Act. This coalition is now hard at work on achieving legislation related to medication administration and collaborative practice.

New Kelly Building to Rise This Year

MPhA and the School of Pharmacy have been working together over the last two years to plan a new Kelly Memorial Building. The University of Maryland Medical System, the private hospital located right in the middle of the University of Maryland campus, is moving forward with Phase III of a massive renovation overhaul and expansion of its medical center physical plant. Phase III involves moving westward along Lombard Street between Greene and Penn Streets. The Hospital has already acquired Parsons Hall and Whitehurst Hall from the University School of Nursing and has demolished these buildings. Dunning Hall, the School of Pharmacy's home for many years until it moved into its building on Pine Street in 1982, will be demolished very soon. The Hospital needs the property on which the current Kelly Building is located to complete their construction footprint.

After arduous negotiations, MPhA has agreed to give up the current Kelly Building in exchange for the Hospital's commitment to build a new modern building on the Maryland campus just north of the police station at Pine and Saratoga Streets. Terms and conditions of the lease would be identical to that of the old Kelly Building with an extension of the lease to 99 years.

In a separate agreement between MPhA and the School of Pharmacy, the School will build the top floor of the building and use it to house the Maryland Poison Center and the Drug Information Center. These two service organizations will occupy about 2400 net square feet in the Kelly Building and will continue to bring its life saving professional services to the citizens of Maryland and to the pharmacy and medical communities.

The new Kelly Building will benefit from a campus location providing its round-the-clock security and a central Baltimore location. The new location will be even closer to Pharmacy Hall making it easier for student and faculty involvement in MPhA activities. This arrangement will provide the School of Pharmacy with much-needed space for information services that are growing dramatically.

The new Kelly Building is a prime example of the synergy that comes from well-planned cooperative efforts.

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Pharmacy and the Law

by
Kenneth R. Baker, B.S.Pharm., J.D.
Vice President, General Counsel
Pharmacists Mutual Insurance Company

When Bad Things Happen—Be Prepared

According to the Gallop poll, pharmacists are the most trusted professionals. This can be a double edged sword. If pharmacists disappoint their patients, the likelihood of a lawsuit may increase because the patient placed so much faith in their pharmacist. "To err is human", but when the mistake is compounded by the manner in which the a pharmacist handles a situation, the result can be even worse. Whether or not the pharmacists acted properly when the mistake was brought to their attention in this 1996 case we do not know, since this ruling only involves the plaintiff's allegations. Whether the pharmacists actions, even if as alleged, would have made a difference, we can only speculate. This case, however, serves as a warning to pharmacists to consider what they would do if they discovered they made a mistake.

The case of Polio v. Derby Center CVS[1] was presented to the Court on a motion by the defendants to strike parts of the complaint dealing with the parent's emotional distress. Of interest are the allegations (unproven at the time of this ruling) by the plaintiffs and what pharmacists can learn from those allegations.

The parents of the child, Dennis, allege the pharmacy negligently filled Dennis' prescription and this caused Dennis "physical harm, discomfort, embarrassment and emotional distress." The unusual parts of the parents' complaint asks for additional damages for failing to identify the incorrect drug when asked and for "failing to render assistance" to the parents "upon learning of their mistake and the physical and emotional harm caused to their son."

If we make a mistake, harm to our patients can result. No pharmacist is immune to the possibility of an error. There are risk management steps we can take to avoid mistakes, but no risk management program can completely eliminate them. Pharmacists can, however, learn to handle mistakes when they happen in a manner that does not cause further harm.

Insurance companies too often stress "never admit you are negligent". This may be sound advise when dealing with an automobile accident, but a professional liability case is different. When confronted with an obvious error, the first rule should be "care for the patient". If the pharmacist discovers an error, the pharmacist should first alert the patient to stop taking the incorrect prescription. If the patient is contacted soon enough further harm may be avoided. The physician must be contacted because a physician treating a patient must know what medication the patient has been taking, even if it is wrong.

Regardless of how many patients are waiting, a pharmacist confronted with a patient who indicates their prescription may be wrong, needs to handle the situation immediately. If their is an error, the pharmacist must identify what and how often the patent took the medication.

If a patient calls the pharmacy with a question as to whether the prescription is wrong, the first thought of the clerk, technician or pharmacist answering the phone may be, "it's just a generic". Claims have resulted which could have been prevented if this answer had not been given. The rule should be, "assume it is an error, until proven to be correct." A clerk or technician should not handle this type call. It must always be given to the pharmacist.

If there is an error, the patient should not be unduly alarmed, but the pharmacist should not make excuses. Telling a patient, "This happens sometimes" is not reassuring. A concerned attitude is a must, even if the patient is wrong.

---

[1] Polio et al. V. Derby Center CVS, Inc. et al. (1996 WL 521133 (Conn.Super.)

If the pharmacist discovers an obvious error, there is nothing wrong with saying, "I am sorry". An obvious error will be easily proved, and an "I am sorry" may help. The pharmacist can not, however, make comments about which he or she has insufficient information.

It is a good idea to try to get back an incorrect prescription in order to avoid any further accidental ingestion of the medication. If the patient refuses to return the incorrect medication, however, the pharmacist usually can not insist that the patient "hand it over". The pharmacist should caution the patient to tape the bottle closed, mark the bottle so no one else will take it and keep the bottle in a safe place. Later, when the matter has been settled, the incorrect prescription can be retrieved and destroyed.

Pharmacists should consider what to do if an error is discovered rather than leaving decisions to be made at a time of stress. Such matters should be discussed with co-workers and employers before they happen.

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This article discusses general principals of law and risk management. It is not intended as legal advise. The pharmacist should consult their own attorney and insurance company for specific advise. The pharmacist should be familiar with their employers and insurance company's policies and procedures and act accordingly.

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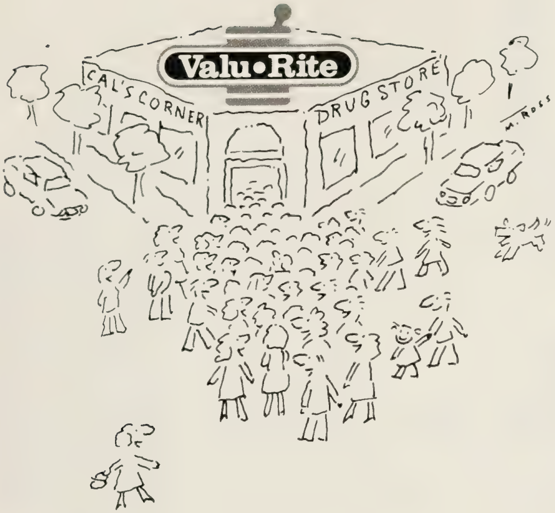

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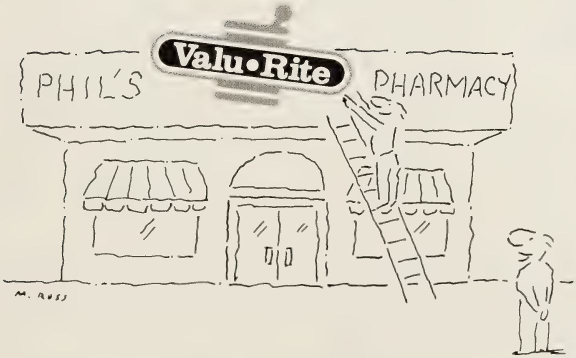

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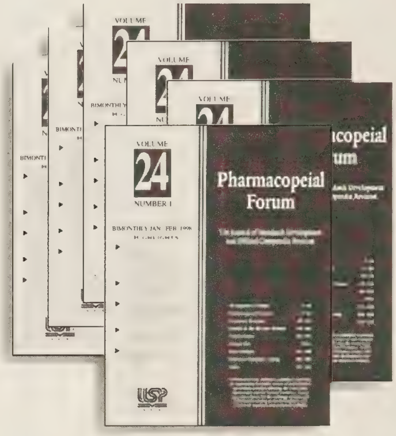

Maryland Poison Center
Univeristy of Maryland School of Pharmacy
1997 Statistical Report

The Maryland Poison Center (MPC) is a division of the University of Maryland School of Pharmacy and is certified by the American Association of Poison Control Centers as a regional poison center for Maryland. In addition, the MPC serves as consulation center for the Maryland Institute for Emergency Medical Services Systems. This report presents an overview of MPC poisoning data for 1997. Additional information is available upon request.

The MPC is saving even more health care dollars by managing more patients safely and inexpensively at home. ***The challenges for the future are to: 1) increase MPC visability in the community; 2) decrease the cost and complexity or care for poisoning patients while maintaining and/or improving outcomes.***

Call Volume

During 1997, the MPC managed 57,189 calls. While 39,065 involved humans, 18,072 calls were requesting information where no human exposure occurred. In only two years, we've seen our hauman case call volume increase by 8.25%. Despite this increase, the percentage of patients safely managed at home increased by over 6.5%.

Age

The majority of poison exposures (54.3%) involve children under the age of six years.

Age (Years)	Number	%
<1	2,466	6.3
1	6,828	17.5
2	6,729	17.2
3	2,914	7.5
4	1,378	3.5
5	898	2.3
6-12	2,914	7.5
13-19	3,160	8.1
20-29	3,093	7.9
30-39	3,586	9.2
40-49	2,188	5.6
50-59	1,172	3.0
60-69	622	1.6
> 70	855	2.2
Unknown Child	7	0.0
Unknown Adult	210	0.5
Unknown Age	45	0.1
Total	**39,065**	**100.00**

Gender

In 1997, 49.5% of exposures involved males, 50.5% were in females, and 0.02% unknown sex of the victim.

Geographic Distribution

Area	Number	%
Allegany	577	1.0
Anne Arundel	7,207	12.6
Baltimore County	11,063	19.3
Baltimore City	10,612	18.6
Calvert	810	1.4
Caroline	306	0.5
Carroll	2,148	3.8
Cecil	995	1.7
Charles	1,076	1.9
Dorchester	283	0.5
Frederick	1,596	2.8
Garrett	297	0.5
Harford	3,045	5.3
Howard	2,871	5.0
Kent	275	0.5
Montgomery	3,915	6.8
Prince Georges	3,039	5.3
Queen Anne	429	0.8
Saint Marys	1,026	1.8
Somerset	156	0.3
Talbot	450	0.8
Washington	1,123	2.0
Wicomico	629	1.1
Worcester	652	1.1
Other/Unknown	2,609	4.6
Total	**57,189**	**100.00**

Circumstance

Acute exposures accounted for 94.2% of the total calls, acute-on-chronic were 4.5% of calls, and 1.3% were chronic exposures.

Unintentional poison exposures were tracked by the Maryland Poison Center and categorized by the type of exposure. These exposures fall into seven categories: general (23,810 exposures, 60.9%); occupational (722 exposures, 1.8%); environmental (686 exposures, 1.8 %); therapeutic error (3,256 exposures, 8.3%); misuse (2,983 exposures, 7.6%); bite/sting (730 exposures, 1.9%); food poisoning (351 exposures, 0.9%; and unknown circumstances (3 exposures, 0.0%). In total, there were 32,541 unintentional poisoning exposures reported to the Center in 1997.

There were 5,674 ***intentional*** poisonings handled by the Center. These included poisonings by suicide attempts (4,636 exposures, 11.7% of total); misuse (568 exposures, 1.5%); abuse (433 exposures, 1.1%); unknown (37 exposures, 0.1%). Intentional poisonings accounted for 14.5% of the cases handled by the Center in 1997.

In addition to general and intentional poison calls, the Maryland Poison Center also intervened in situations where poisonings occurred for ***other*** reasons. 56 exposures (0.1% of total) were due to contamination and/or tampering. 136 poisonings (0.4%) were determined to be of malicious intent. Adverse reactions to drugs, foods, and other products accounted for an additional 644 calls to the Maryland Poison Center. There were 14 unknown exposures (0.0%).

Site of Exposure

Not surprisingly, the vast majority of poisonings occur at home. According to the statistics gathered, poisonings occurred at the: residence (36,671, 93.7%); workplace (922, 2.4%); school (784, 2.0%); public area (294, 0.8%); health care facility, (62, 0.2%); restaurant (38, 0.1%); other, (264, 0.7%); unknown (30, 0.1%).

Treatment Location

75.2 percent or 29,395 cases of poisonings were treated in non-healthcare facilities. The Maryland Poison Center referred patients to health care facilities for treatment in 6.3% of 39,065 cases. The outcomes of those referrals are:

Treated & Released	1,314
Admitted for Medical Care	231
Admitted for Psych Care	160
Refused referral	568
Lost to Follow up	195

Of patients already in health care facilities, the outcomes of those referrals are:

Treated & Released	3,821
Admitted for Medical Care	1,621
Admitted for Psych Care	1,078
Lost to Follow up	195
Total Already in HCF	6,715
Other	463
Unknown	24

Route of Exposure

The vast majority of poisonings occurred from taking agents orally (32,221 cases, 75.5%); ocular (2,688, 6.3%); dermal (4,651, 10.9%); inhalation (1,899, 4.4%); bite/sting (736, 1.7%); parenteral (158, 0.4%); aspiration (292, 0.7%); other (37, 0.1%); unknown (15, 0.0%). Total 42,697 cases.

Note: The total cases by route of exposure is greater than the number of cases reported. This is because some patients had more than one route of exposure.

Medical Outcome

The medical outcome is assessed based on the inherent toxicity of the agent and the severity of the clinical manifestations. In 29,095 cases (74.5% of total), the agent was non-toxic or had no adverse health effects on the patient. Minor/minimal effects were reported in 6,726 cases (17.2%), moderate effect in 1,565 cases (4.0%), major effect in 152 cases (0.4%), death in 25 cases (0.0%), unrelated effect in 842 cases (2.2%), and unknown/potentially toxic in 660 cases (1.7%).

Deaths

The Maryland Poison Center was consulted on 24 patients who died as a result of the poisoning.

Age (Years)	Sex	Substance
6	F	Oxycodone, Imipramine
15	F	Gasoline
16	M	Butane
20	M	Ethanol
30	M	Paraquat
36	M	Promethazine, Methadone
37	M	Sulfuric acid
40	F	Methanol
41	M	Ethylene glycol
42	F	Amitriptylline
42	M	Cardizem CD, Mevacor
43	F	Unknown
43	M	Acetaminophen
47	M	Diphenhydramine
48	F	Perfume
50	M	Acetaminophen, Percocet
50	M	Acetaminophen, Percocet
51	M	Carbon monoxide
52	M	Kitty litter, Lithium
53	F	Morphine, Fioricet
58	M	Nortriptylline, Fluvoxamine, Lorazepam
63	M	Acetaminophen, Ethanol
77	F	Triavil, Atenolol, Alprazolam
81	F	Salmonella
90	F	Meprobamate, Doxepin

Agents	Number	%
Drugs		
Analgesics	3,171	
Anesthetics	110	
Anticholinergics	69	
Anticonvulsants	535	
Antidepressants	1,416	
Antihistamines	809	
Antimicrobials	848	
Asthma therapies	311	
Cardiovascular drugs	991	
Cough & Cold preparations	1,931	
Diuretics	49	
Electrolytes/minerals	259	
Eye, ear, nose, throat preparations	65	
Gastrointestinals	1,040	
Hormone products	648	
Muscle relaxants	201	
Sedative hypnotics/Antipsychotics	1,567	
Stimulants/Street Drugs	684	
Topicals	1,322	
Veterinary products	67	
Vitamins	906	
Miscellaneous	632	
Unknown Drugs	17	
Total: Drug Products	***17,648***	***44.6***
Non-Drugs		
Alcohols	1,212	
Arts, Crafts, Writing Products, Office Supplies	1,161	
Automotive products	244	
Batteries	107	
Bites & envenomations	815	
Building/Construction Products	138	
Chemicals	993	
Cleaning Substances- Household	3,646	
Cosmetics/personal care	4,471	
Deodorizers	314	
Fertilizers	76	
Fire Extingushers	75	
Food/ Food poisoning	307	
Foreign Bodies	2,036	
Fumes, gases, vapors	703	
Heavy Metals (excluding iron)	57	
Herbicides	61	
Hydrocarbons	965	
Insecticides	603	
Lacrimators	77	
Mothballs	300	
Mushrooms	103	
Paints, Varnishes, Lacquers	533	
Plants	2,026	
Polishes and Waxes	156	
Rodenticides	275	
Swimming pool/Aquarium Products	110	
Tobacco products	145	
Miscellaneous/Unknown Substances (Non-Drugs)	256	
Total Non-Drugs	***21,965***	***55.4***
Total Agents	**39,613**	**100.00**

Educational Programs

The Maryland Poison Center offers a statewide program of hospital in services and presentations at grand rounds, paramedic training classes and EMS conferences. Poison center staff conducted 19 presentations in 1997. Toxalert, a newsletter for health professionals, offers current toxicity and treatment information on a variety of topics as well as the MPC's annual report. The MPC also acts as a training site for pharmacy, nursing and paramedic students, emergency medicine, family practice and pediatric residents and fellows, and pharmacy residents. The MPC provides public education through presentations, displays, brochures, Mr. Yuk stickers, audiovisual materials, Teacher's Resource Kits and interaction with the media.

Maryland Poison Center Advisory Board

The following individuals gave their time and energies to help provide guidance and support to the Maryland Poison Center Advisory Board:

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Save the Independent Pharmacists!

Daniel A. Hussar, Ph.D., Chief Pharmacy Editor of Pharmacy Today;
Remington Professor of Pharmacy, Philadelphia College of Pharmacy

I grew up in a Philadelphia neighborhood that had seven independent pharmacies and seven independent grocery stores within a mile of my home. Now there are none.

The grocery stores closed first, as supermarket chains came into the area. And, one by one, for a variety of reasons, the independent pharmacies also closed.

An endangered species?

This editorial is not intended to predict the disappearance of independent pharmacies. Indeed, many have not only survived; they have thrived in the face of the many changes that have occurred in health care and the business community in recent years. However, the number of independent pharmacies has unquestionably decreased markedly, and the rate at which they have closed or been sold to chain pharmacies within the past tow years is unprecedented. Give this rapid decline in numbers, independent pharmacies should qualify as an "endangered species."

The concept of endangered species and programs such as "Save the Whales" are familiar to us because of concerns that certain animals and birds will become extinct if steps are not taken to protect them. Actions to save the whales, and even the snail darters, are noble purposes worthy of people's attention. But I find it ironic that our society has essentially been silent regarding the risk of the disappearance of many small businesses, including independent pharmacies. It is no exaggeration to suggest that the vitality of a community may be severely compromised by the closing of independent pharmacies and other small businesses. In many cities, as well as smaller towns, boarded-up buildings now stand where once were thriving business communities.

Some say that the increase in the number of chain pharmacies compensates for the loss of these independent pharmacies. But they are not the same. Independent pharmacy owners make personal, financial, and long-term investments in the community and usually reside there, often assuming leadership responsibilities and becoming well known and highly respected. As dedicated as chain pharmacists may be, they rarely have a personal financial investment in the community. And they often experience working conditions that preclude substantive discussions with individual patients, are subject to transfer to other pharmacies within the chain, and are more likely to accept a position with another employer.

Why are independents at risk?

Plenty of blame for the closing of independent pharmacies can be spread around, but let's start with ourselves.

- Too satisfied with the status quo, many independent pharmacists have been unwilling to update themselves and their pharmacies to stay competitive in a changing health care and business environment.
- Pharmacists are not making their patients aware of the challenges being faced and are not providing patients with the information they need to recognize that these issues affect the quality of their own health care.
- Pharmacy schools and associations have not done enough to prepare students and pharmacists to respond to the changes, problems, and opportunities they encounter.
- Some chains have been predatory in intimidating independent pharmacy owners to sell immediately, indicating that the independents are unlikely to survive and that no one will buy their pharmacies later.
- Some pharmaceutical companies have pricing policies that are unfair to community pharmacies, and they have opposed legislation that would expand pharmacists' practice responsibilities and increase the value of their service.
- The programs of some insurance and managed care organizations exclude the participation of certain pharmacies, or permit participation only if the patient assumes added costs. The "take it or leave it" reimbursement programs dictated by many of them present a dilemma for pharmacists: they cannot afford to participate under such programs' financial terms, but they also cannot afford to decline to participate in programs to which many of their patients belong.
- Legislators and government agencies permit the continuance of outdated laws and systems that allow other entities to dictate levels of pharmacist reimbursement and stop pharmacists from collectively negotiating the terms of such programs. Isn't the Small Business Administration supposed to advocate for and protect the interests of small business?
- Our patients are not protecting their freedom to choose a pharmacy and other health care providers, and they are not doing enough to be advocates for the independent pharmacies in their communities.

Send *Pharmacy Today* your ideas. Is it too late?
No! But we must act quickly and aggressively to address these letters. Pharmacy Today welcomes your ideas as to how this can best be accomplished. Save the independent pharmacists!

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Continuing Education for Pharmacists

Volume XV, No. 8

Patient Counseling: Prevention and Treatment of Skin Injuries; Part 2: Poison Ivy, Prickly Heat, and Diaper Dermatitis

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Goals. The goals of this lesson are to discuss common dermatologic conditions that are self-treatable with skin protectants, and to present information useful in counseling patients.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify the causes and etiology of the conditions described;
2. exhibit knowledge of the treatment and means to prevent the conditions described;
3. show an understanding of the pharmacologic actions and adverse effects associated with the drugs used to treat the conditions; and,
4. demonstrate an ability to counsel patients on prevention and treatment of each of the conditions described.

Gossel

Wuest

Poison Ivy, Oak, and Sumac

Allergic dermatitis is reported to be an outcome of contact with approximately 60 plants in the U.S. Poison ivy and oak are the leading causes of allergic dermatitis. The rash that results from contact with either plant is similar. Poison sumac causes comparable problems, but they are less common than those associated with poison ivy or oak. Most estimates state that at least 70 percent of Americans are allergic to these plants.

Poison ivy and oak reactions that follow contact with the oleoresin complex urushiol may be experienced throughout the year. They are much more common during the early spring and summer months, however, when plant growth is most active. Most questions about preventing and treating poison ivy and oak dermatitis reactions are asked during these seasons. The following information can be used in responding to these inquiries.

Treatment. Numerous home remedies have been formulated and proprietary products marketed over the years to help relieve symptoms of poison ivy and oak dermatitis. Many treatments that have not been proven safe and/or effective in modifying urushiol-induced skin reactions continue to be recommended and used widely. It should be noted that, at most, they may relieve itching and thus help protect underlying skin indirectly from damage by scratching.

Relief from itching is the primary goal of therapy. If itching is not checked, the sufferer may scratch the skin insatiably and damage it.

Rash and associated symptoms are usually self-limiting, normally clearing within one to three weeks with or without treatment. Unless secondary infection occurs, healing proceeds without serious complications.

Complications can occur including hematologic changes, kidney damage, dyshidrosis (lack of sweating), and pigment changes. Psychologic reactions may be reported if the reaction is severe. For severe reactions, patients should be directed to a physician and advised not to self-treat their condition with OTC products. Usually a short-term course of corticosteroids is the best treatment.

Even though it is a widely held belief, the exudate of poison ivy or oak dermatitis does not spread the condition. When blisters form, it may be beneficial to drain them carefully. Removing this fluid permits topically applied medications to penetrate more readily into the dermis where the stimulus for itching originates. It also eliminates some of the pressure from above the nerve endings to help relieve itching.

Draining is best achieved by

Table 1
Patient Information for OTC Topical Hydrocortisone

Topical hydrocortisone is used for temporary relief of minor skin irritation, inflammation and rashes due to eczema, psoriasis, seborrheic dermatitis, poison ivy, oak, or sumac, insect bites, soaps, detergents, cosmetics or jewelry, and external genital and anal itching.

- To properly use this product:
  - a. Wash your hands before and after use.
  - b. Cleanse the skin area with soap and water and pat dry each time you are ready to apply this medicine, unless directed otherwise by your doctor.
  - c. Only the medicine that is actually touching the skin will work. A thick layer is not more effective than a thin layer.
  - d. Creams, ointments and lotions: Apply a small amount of the medicine to the affected area and spread lightly.
  - e. Lotions: Shake the container well before applying the medicine.
- This product is for external use on the skin only. Do not apply it into or near your eyes or mouth.
- Do not apply other creams, lotions or cosmetics on top of or underneath this medicine.
- Do not bandage the area unless directed by your doctor.
- If your condition persists or worsens, or if you have a constant irritation, such as burning or itching that was not present before you started this medicine, call your doctor.
- Do not use more often or longer than recommended on the label.
- Read all labels before using this product. If you have any questions, ask your doctor or pharmacist.
- Keep all medicines out of the reach of children and do not keep or use outdated medicines.

inserting a needle at the blister margin on the skin's surface using aseptic technique, then applying slight pressure to the blister top to express the liquid. Extruded fluid can be absorbed onto tissue or gauze or simply washed off. To help protect the tender underlying skin, the skin covering the blister should not be removed. Blisters on the face or genitals should be opened only by a physician.

Poison ivy and oak remedies may contain local anesthetics which interfere with generation and transmission of nerve impulses. Care should be observed when using any product containing benzocaine because it may incite sensitivity reactions in susceptible individuals. Most references which refer to the incidence of benzocaine-induced skin reactions are conflicting, and this incidence may be over-estimated. Nonetheless, patients sensitive to poison ivy and oak, who also respond to contact with other chemicals with allergic rash, should avoid benzocaine-containing products.

Antiseptics help prevent secondary infection. If itching is controlled so that tissue damage from prolonged scratching is minimized, infection is rarely a problem. Products with alcohol or phenol as the antiseptic are preferred, since these are also antipruritic. Benzalkonium chloride is inactivated by soap, so it is doubtful whether this antiseptic offers significant activity to warrant inclusion in OTC poison ivy and oak products.

Astringents include zinc and ferric oxides, potassium permanganate, tannic acid and aluminum acetate. These precipitate protein over the lesion, which causes the underlying area to contract and dry. Astringents also have mild antiseptic and tissue protecting actions. Except for aluminum acetate, the antipruritic action is not significant.

The switch of topical formulations of hydrocortisone from prescription-only to OTC status has increased self-treatment options for poison ivy/oak greatly. Patient information is listed in Table 1.

Benzoquatam is a newly-approved drug with a mechanism of action different from any other approved substance used to prevent poison ivy and oak allergic reactions. Also known as quaternium-18, benzoquatam is prepared by reacting a quaternary ammonium compound with bentonite (a clay). The resulting organoclay compound acts as a physical barrier to block contact of urushiol with the skin.

The OTC product (IvyBlock) is available as a 5 percent lotion. It is applied to the skin at least 15 minutes before possible exposure to poison ivy or oak. Patients should be advised to shake the container vigorously before applying. They should reapply the product every four hours for continued protection. Since it contains alcohol, the lotion should not be used around open flames.

Prickly Heat

Lesions of prickly heat (miliaria, heat rash) were described nearly 2000 years ago. Amelius Cornelius Celsus (25 B.C. to 50 A.D.) wrote about the pustules that appeared with sweating in his work entitled *DeMedicina*. Later, Pliny the Elder wrote of pimples caused by sweat in his treatise entitled *Natural History*.

Today we know that prickly heat is caused by obstruction of sweat gland openings. Sweat is trapped within the dermal layer causing localized irritation and inflammation, itching and generalized discomfort. The term *prickly* describes sensations variously referred to as *stinging or stabbing*. The disorder is visible as clusters of pinhead-size bumps.

Prickly heat is most prevalent during humid periods with temperatures above 90°F and low wind velocity. It may appear during febrile illness when the skin is covered with heavy or obstructive clothing that causes intense sweating. Skin areas subjected to friction, such as the belt line or skin underlying elastic edges of athletic work-out garments, are especially vulnerable. The condition also occurs when individuals sit or lie for extended periods on rubber or plastic sheets which retard sweating.

There are several types of prickly heat. *Miliaria crystallina* describes the condition caused by sweat duct obstruction within the stratum corneum, just beneath the surface of the skin. A large vesicle, one to two millimeters in diameter, forms over the skin surface. This condition occurs on the neck, underarms, and chest of infants, although it can appear on individuals of all ages. Lesions are usually asymptomatic until they are broken open by rubbing or scratching. Lesions filled with clear fluid, which can be broken easily with the fingernails, are characteristic of *miliaria crystallina*.

Miliaria rubra describes the condition when obstruction occurs deeper within the epidermis. The name is appropriate because of its red coloration. *Miliaria rubra* may be confused with contact dermatitis or drug eruption. It is the only form of prickly heat characterized by inflammatory lesions. Sweating causes small red nodules (solid bumps) that overlay red vesicles. Itching and burning quickly follow any event which induces sweating.

Miliaria profunda describes obstruction of the sweat duct within the upper dermis. This condition occurs predominately on the trunk and upper legs. It results in flesh-colored or opaque papules. *Miliaria profunda* is often asymptomatic, and waxes and wanes with sweating episodes.

Although sometimes referred to as "gooseflesh," *miliaria profunda* should not be confused with *cutis anserina*. This is an evanescent (i.e., disappears quickly) follicular disorder associated with cold and shock, rather than heat and sweating.

Any injury to the sweat duct can cause obstruction to sweat flow. Therefore, the patient may remain asymptomatic until sweating is stimulated and not necessarily relate the condition with the trauma that actually caused it.

Prickly heat occurs more frequently in infants, geriatrics, and other persons with atopic disease than in young and middle-aged adults. *Miliaria crystallina* generally clears quickly without complications, with or without treatment.

Miliaria rubra may persist for two to three weeks while sweat ducts remain obstructed. With repeated skin damage, as that caused by persistent scratching, additional pathology appears, leading to *miliaria profunda*. Secondary infection may occur with *miliaria rubra*, including impetigo and folliculitis. It is, therefore, important to keep affected areas clean at all times.

When widespread obstruction to sweating occurs, as when 50 percent or more of the body surface is affected, anhidrosis (cessation of sweating) may result. In hot environments when body temperature regulation depends on properly functioning sweat glands, this may lead to serious complications.

Prevention and Treatment. Miliaria is best treated by preventing any stimulus that initiates sweating. This is accomplished by remaining in a cool environment and avoiding heavy work or exercise. Air conditioning may help individuals who are severely affected.

The patient's clothing should be loose fitting, light-weight, and absorbent. During periods when prickly heat is exacerbated, plastic diaper covers (rubber pants) should not be worn by infants.

Cool sponge baths with a colloidal oatmeal product followed by application of a cooling skin lotion are often helpful. Hydrocortisone lotion or cream may help reduce local inflammation causing obstruction, but hydrocortisone should be reserved for individuals two years of age and older, unless specifically requested by a physician.

Diaper Dermatitis

Diaper dermatitis (diaper rash, napkin rash, napkin dermatitis, nappy rash) is the most common skin eruption of the diaper area. An assessment of one-week-old infants showed that 35 percent had perianal dermatitis. Incontinent adults may experience similar irritant dermatitis.

Diaper rash is different from prickly heat, although they may appear the same physically. Diaper rash is also confused with other cutaneous disorders including candidiasis, dermatitis, psoriasis, scabies, and herpes simplex. Specifically, diaper rash is a localized, red, inflammatory response that results from dermal contact irritation caused by urine, feces, or both.

Occasionally the rash may appear on areas other than those in contact with a diaper, such as the arm or face. When this occurs, it represents involvement of some factor other than the primary affliction causing the diaper rash. Infants with this condition should be examined by a physician before being treated with OTC remedies.

Diaper rash is categorized into four distinguishable forms. The most frequent is chafing dermatitis, noted by mild redness and scaliness over the buttocks, waist and thigh-areas where the diaper touches the skin. A second type is sharply demarcated confluent redness confined to the skin folds. A whitish exudate is sometimes present.

In the third form, discrete, shallow ulcerations are noted over the entire diaper contact area. The fourth form is characterized by beefy-red confluent erythema over the diaper area with oval pustules around the outer edge of the confluent area. This type of condition is compounded by fungal infection characteristic of *Candida albicans* (ulcerations with white exudate).

Diaper dermatitis is an irritant response that results when skin remains in continued contact with urine and/or feces. While variations occur, many experts attribute eruptions in the perianal area to

Table 2
Safe and Effective Skin Protectants

Ingredient	Concentration
Allantoin	0.5-2%
Aluminum hydroxide gel	0.15-5%
Calamine	1-25%
Cocoa butter	50-100%
Colloidal oatmeal	
Dimethicone	1-30%
Glycerin	20-45%
Kaolin	4-20%
Petrolatum	30-100%
Shark liver oil	3%
Sodium bicarbonate	1-100%
White petrolatum	30-100%
Zinc acetate	0.1-2%
Zinc carbonate	0.2-2%
Zinc oxide	1-25%

feces, and rash on the waist, thighs and genitals to urine. Studies have investigated individual components of feces and urine to show which is responsible for the dermatitis. None of them has established an absolute cause-and-effect relationship.

Mechanical irritation also plays a role in development of dermatitis on the buttocks and other areas of pressure from the diaper. Irritation results when a diaper rubs against the skin constantly. It is increased when the diaper is fastened tightly, and characterized by a strong odor of ammonia.

Prevention and Treatment. Diaper dermatitis may be prevented and/or treated with the skin protectants listed in Table 2. Products containing zinc oxide and/or petrolatum are among the most effective and widely used remedies.

Products containing topical hydrocortisone (up to 1 percent, preferably 0.5 percent) are safe and effective for short-term application on children aged two years and above. Use should be restricted to less than one week to minimize risk of systemic toxicity from absorption. Absorption is enhanced by occlusion with rubber or plastic pants. Used correctly, steroid toxicity from hydrocortisone is rare. When toxicity is reported, it is usually in infants who are preterm, of low birth weight, or have severe inflammation or extensive denuded areas of skin in the diaper area.

Routine use should not be relied on since hydrocortisone treats symptoms without modifying their cause. Other OTC products containing a protectant such as zinc oxide should be tried first.

Boric acid has a long history of topical use on infants. It can be absorbed across irritated skin. Because of reported infant toxicity and fatalities, it should not be used to treat diaper dermatitis.

In some studies, quaternary ammonium compounds such as methylbenzethonium chloride have been shown to reduce occurrence of diaper dermatitis. But other studies have questioned their effectiveness, and some have actually shown them to cause irritation in the diaper area.

A candidal infection is suggested when there are isolated areas of dermatitis on the skin. These should be examined by a physician. Dermatitis that persists beyond 72 hours should also be evaluated professionally since there is increased association with *C. albicans* after this period.

The need for frequent diaper changes must be stressed to parents/caregivers. The diaper should be changed as soon as possible after it becomes wet. The diaper area should be cleansed thoroughly with warm water and mild soap, and dried completely before a clean diaper is put on.

"Dry" diaper corners should not be used to wipe the baby's skin. Although they appear clean and dry, they may contain millions of microorganisms. If these microorganisms are not removed by cleansing, the chance for infection is increased when the baby urinates the next time.

Infants who are highly susceptible to diaper rash may be placed on an open diaper during naps. Babies frequently urinate shortly after falling asleep. Therefore, they can be checked and the diaper replaced periodically if necessary.

Counseling Patients

Consumer-directed advertising strongly suggests that certain types of diapers are better than others. The more fluid the diaper absorbs, the less contact it has with the skin. No study has demonstrated significant benefits of cloth over disposable diapers and vice versa.

Significant differences can be shown between commercially laundered and home laundered diapers. Commercial laundry services clean diapers at high temperatures which destroy all microorganisms very effectively. They also remove chemical irritants afterwards with thorough rinsing. These diapers are as clean and sterile as possible.

Individuals who wash diapers should use hot water, followed by thorough rinsing and drying in the hot cycle of the clothes dryer. Soaking diapers in a household bleach solution (diluted as directed on the label) or vinegar (one cup vinegar in a half-filled washing machine tub) prior to washing may help reduce the potential to irritate the skin.

Diaper dermatitis will not be experienced by all infants and incontinent individuals. OTC products intended for prevention and/or treatment of diaper dermatitis are not necessary for prophylactic use. These products ordinarily should not be used continuously.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Prevention and Treatment of Skin Injuries; Part 2: Poison Ivy, Prickly Heat, and Diaper Dermatitis." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 8/15/00. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-97-008-H01.

Name______________________________________

Address____________________________________

City, State, Zip_______________________________

The Maryland Pharmacy Continuing Education Coordinating Council and the Ohio Pharmacists Foundation are both approved providers of continuing pharmaceutical education for pharmacists by the American Council on Pharmaceutical Education.

ACPE®

1. Diaper rash is caused by:
   a. a bacterial infection.
   b. a malfunction of the heat regulation mechanism in the hypothalamus.
   c. contact irritation reaction.
   d. obstruction of sweat gland openings.

2. Diaper rash is best prevented and/or treated by:
   a. using a skin protectant to prevent contact with the causative irritant.
   b. applying a first aid topical antibiotic ointment.
   c. preventing any stimulation that initiates sweating.
   d. taking aspirin as long as the child does not have a viral infection.

3. The oleoresin complex in poison ivy that causes allergic reactions is:
   a. plantago.
   b. cytosine.
   c. rhus toxica.
   d. urushiol.

4. All of the following are true about the blocking agent containing benzoquatam EXCEPT:
   a. it acts as a physical barrier.
   b. it is a clear solution.
   c. it should be applied prior to exposure to poison ivy.
   d. it should be reapplied every four hours for continued protection.

5. The primary goal of therapy with poison ivy is to:
   a. protect the blisters.
   b. prevent systemic toxicity.
   c. relieve itching.
   d. reduce fever.

6. Prickly heat is caused by:
   a. a bacterial infection.
   b. a malfunction of the heat regulation mechanism in the hypothalamus.
   c. contact irritation reaction.
   d. obstruction of sweat gland openings.

7. Prickly heat is best prevented and/or treated by:
   a. using a skin protectant to prevent contact with the causative irritant.
   b. applying a first aid topical antibiotic ointment.
   c. preventing any stimulation that initiates sweating.
   d. taking aspirin as long as the child does not have a viral infection.

8. Which of the following is the preferred antiseptic to prevent secondary infections to poison ivy dermatitis?
   a. Alcohol
   b. Benzalkonium chloride
   c. Neomycin
   d. Polymyxin

9. Prickly heat lesions filled with clear fluid, which can be easily broken, are characteristic of:
   a. *miliaria crystallina.*
   b. *miliaria profunda.*
   c. *miliaria rubra.*

10. The exudate of poison ivy dermatitis:
   a. spreads the condition.
   b. does not spread the condition.

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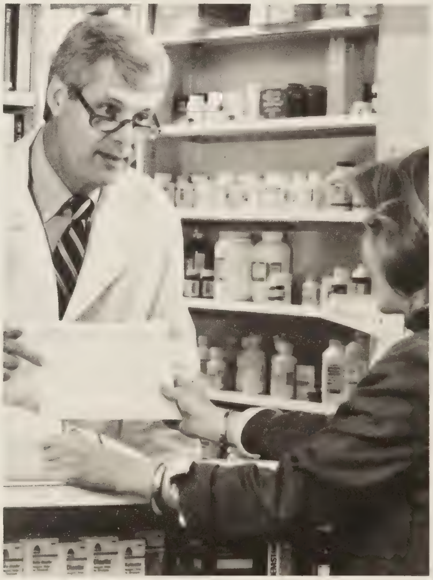

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Outcomes Data for Pharmacist-Managed Anticoagulation Clinics

University of Maryland School of Pharmacy
Sonia Kim, Pharm.D. Student

With increased emphasis on pharmaceutical care, documenting outcomes is vital to achieving widespread acceptance of pharmacist management of patients. This paper will review and discuss the data on outcomes for pharmacist-managed anticoagulation clinics (PMACs). PMACs have been in existence for over 20 years.[1] In PMACs pharmacists are responsible for managing all aspects of a patient's warfarin therapy. Specially trained pharmacists obtain patients' medical and drug histories, monitor vital signs, obtain and monitor PT/INR values, provide patient education and counseling, adjust warfarin dosing, and triage patients to other health professionals as necessary.

One of the earliest published evaluations of a PMAC looked at outcomes during a nine-year period. Conte et al. analyzed 1792 PT values for 140 patients.[1] Of all the prothrombin-time (PT) measurements, 59.2% were within the therapeutic range, 12.4% were above the therapeutic range, and 28.5% were below the therapeutic range. The authors also reported that 82% of patients had therapeutic PT values ≥ 50% of the time. The incidence of minor hemorrhage was 30% and major hemorrhage 2.8%. This study did not include a control group, and therefore, no conclusions could be made regarding improvement of anticoagulation control under pharmacist care. However, the authors stated that the "level of anticoagulation control and morbidity…was acceptable to physicians."[1] The authors cited increased time for counseling as one major advantage of pharmacist-managed anticoagulation clinics. This time for counseling made the most difference in patients that were having problems with compliance.

Another study compared the quality of outpatient anticoagulation when patients were managed by trained pharmacists versus junior medical staff.[2] During a sixteen month period, a retrospective analysis of 2219 INR results for 382 patients was performed. The authors found no difference in the proportion of patients in or out of therapeutic range. However, patients who were out of therapeutic range had a better chance of being brought back under control with the pharmacist's care. The authors attributed this difference to continuity of care. The pharmacists had a decreased turnover rate compared to rotating junior medical staff, received specialized training in warfarin therapy, and followed set protocols for patient management.

The results from a retrospective evaluation of the Long Beach Veterans Administration Medical Center showed a greater percentage of patients had therapeutic PT values and fewer required hospitalizations after the institution of the PMAC than before its institution.[3] The mean percentages of PT measurements out of therapeutic range for the 26 patients in the study were 35.8% preclinic and 14.4% while under PMAC care. The preclinic rate of hospitalization was 39%, while hospitalization rate during clinic management was only 4%. The pharmacists at the same clinic performed a cost-benefit analysis of 26 patients under clinic care and 26 other patients who were not under clinic care.[4] They reported a 70 fold difference in hospitalization days between the control and treatment groups (3.22 vs. 0.048 days per patienttreatment year, respectively.) The treatment group had reduced hospital costs of $211,776 per year.

The Anticoagulation Monitoring Service (AMS) at Family Practice Medical Group, Inc. at the University of Florida compared pharmacist-managed patients against patients of physicians without pharmacist intervention.[5] A retrospective chart review evaluated the number of thromboembolic events, hemorrhagic events, unplanned clinic visits, ER visits, and hospital admissions. The control group was 20 times more likely to suffer a thromboembolic or hemorrhagic event. Assuming the control would not have suffered any major events under the AMS, a cost analysis that included hospital admissions, ER visits, and the anticoagulation service revealed that the use of AMS would have avoided $4,072.68 per person-year of followup.

Improved patient outcomes under pharmacist-management have played a role in expanding the degree of pharmacist involvement in inpatient anticoagulation. Ellis et al. hypothesized that a pharmacist-managed inpatient warfarin-monitoring service would improve physicians' prescribing habits, increase referrals to anticoagulation clinic, improve compliance through education, and decrease the number of ER visits and hospitalizations.[6] Although physician prescribing patterns were similar before and after starting the inpatient service, improved PT stability, increased referrals to the PMAC, and improved compliance in clinic visits for patients with no history of drug abuse were seen for the treatment group. Because of the small number of patients in the study, no significant difference between the two groups was seen for ER visits and hospital readmissions.

One recent study presented at the 1997 ASHP Midyear Meeting looked at pharmacy-initiated dosing of warfarin versus ad hoc therapy initiation in the treatment of deep vein thrombosis, pulmonary embolism, myocardial infarction, and transient ischemic attack/cerebrovascular accident.[7] The study found that pharmacy-initiated dosing showed trends toward increased length of overlap between heparin and therapeutic warfarin therapies, decreased risk of adverse events, and decreased costs.

Overall, these results from various outpatient PMACs and inpatient monitoring services show that not only are the outcomes acceptable or comparable to patient management under physicians, but the outcomes exceed those obtained from other methods of patient management. More patients are controlled under the pharmacists' care, and when not controlled, they are more likely to be brought under control. Improved anticoagulation control translates to fewer hemorrhagic or thromboembolic events as shown by these studies, resulting in substantial cost savings due to decreased ER visits and hospitalizations.

These results, showing improved management of anticoagulation therapy under the care of trained pharmacists, reinforce the benefits of pharmaceutical care. Clinical pharmacists are an integral part of the medical team. As more studies how improved outcomes with pharmacist interventions, the pharmacist's role will continue to expand, and ultimately patients will reap the benefits of improved drug therapy and better disease management.

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Maryland Pharmacist

The Official Publication of the Maryland Pharmacists Association

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President's Commentary

Gerard A. Herpel, P.D.

What is a pharmacist? If you asked your patients this simple question, *what would their answer be?*

- A Health Care Provider who offers easily accessible specialized care and services?

or

- The person behind the counter who wears a white coat and counts the pills?

Do patients really understand what the role of a pharmacist is? Do they know that if given the chance a pharmacist could offer other services such as Immunizations, Bone Density Scanning and Cholesterol Screening? This is what faces our profession as we step into the 21st century. Many states have given the pharmacists the opportunity to expand their practices and offer these and many other services. Just across the Potomac River in Virginia, pharmacists provide many of these same services to their patients.

Imagine this scenario—a patient, Mr. Smith, comes into your pharmacy to get a refill on his Lipitor—there are no refills left and the doctor wants to first have Mr. Smith's cholesterol levels checked. Instead of him going to the doctor's office, his blood would be checked in the pharmacy and the report faxed or e-mailed to the doctor. The doctor then authorizes the refill. You can now collect fees for the prescription, the cholesterol screening, and possibly for patient education or counseling. *Sounds great! But, not in Maryland!*

Pharmacists are rated the "Most Trusted Professional." Our patients will trust the pharmacist to provide these important services in their own communities.

Last year in a House Committee meeting in Annapolis Leo Mallard, legislative co-chairman, perhaps best said it, "It seems as if there are signs at our borders that say Welcome to Maryland —Innovation Stops Here." But, does it really have to?

We must go through the legislative process to accomplish our goals. Nevertheless, we *can* shape our future. This is where we, members of MPhA and others in our profession, come in. As the process evolves we must collectively raise our voices and be heard. When that time comes, don't let our chance slip by. Let's win the battle.

The power every Pharmacy and Pharmacist has is grassroots politics. This is the one power other interest groups do not have. How many patients or customers (*voters)* come through your doors every day? Whether you are working at a chain or independent practice, you interact with hundreds of voters daily. These people respect us and are interested in issues that would improve both their healthcare and, in turn, our practices.

When the time comes it will take a huge effort on all our parts. Calling your legislator's office or writing a letter goes a long way in helping the cause. Another way is informing and enlisting the help of our patients and other pharmacists. We cannot sit idly by and expect things to happen. It takes work and effort.

Pharmacists in Maryland should be in the forefront with our colleagues from other states to provide easily accessible specialized care and services.

Director's Column

Howard R. Schiff, P.D.
Executive Director

After 40 plus years as a community pharmacist, some have asked me why I accepted the position as MPhA executive director. The answer is simply because I wanted to. There are times in everyone's life when a fork in the road is reached and a decision has to be made to take the familiar road or to accept a challenge of something different. The question I asked myself when offered the job was whether I had the energy to take the challenge. The more I thought, the more enthusiastic I became and I knew that I had to take the job or kick myself forever.

What are the personal challenges?

I've spent my life behind a prescription counter being task (℞) oriented. I've never had an office job. This work does not have the immediacy of a prescription. Nevertheless, it does require work in the form of planning, creativity, responsibility, and politicking. The phones may not be ringing off the hook when I open the door, but the tasks take longer to finish and I have to develop the necessary skills. I may be a rookie in the office, but I know pharmacy and I know Maryland pharmacists.

What are the challenges that MPhA faces?

Memberships and fund raising are problems with every volunteer organization. We are no different. Pharmacies in Maryland need a united voice to speak for pharmacists as practitioners not as a vested interest. MPhA represents the profession, not a store or a chain. If it were not here, it would have to be invented to do the job.

Additionally, negotiations are ongoing for our new building, a process that has taken about two years to this point. When the building is finished, MPhA would like to have all the pharmacy organizations in Maryland under one roof so as to provide a common ground on which leaders in Maryland pharmacy can meet to ensure unity for the profession in Maryland.

What are our assets?

Our best assets are the member pharmacists. Again we represent no vested interests. As the future of pharmacy, *as a patient oriented profession* evolves, we want to be the vehicle through which the individual pharmacist can contribute his or her voice. We must aggressively advocate the way we will be practicing in the new millennium. *If you care about your livelihood your best way to express your opinion will be through this organization.*

In a few more weeks I might become accustomed to sitting while working, but I don't think I'll ever be as comfortable as I was filling a prescription.

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Liver Protection & Milk Thistle

Essential to health and vitality, the liver never stops working to regulate metabolism and detoxify substances taken in via the respiratory, digestive or circulatory systems. Ironically, the liver's normal workhorse activity—even in the presence of significant tissue deterioration—can result in serious liver damage before symptoms are recognized.

Liver disease ranks third among disease-related causes of death in adults aged 25 to 59. Millions of people today are infected with chronic hepatitis—and the incidence of both hepatitis B and C (HBV and HCV) is increasing, as are drug and alcohol-related liver disorders and poisoning from exposure to heavy metals and toxic chemicals.

Symptoms of liver disease may include frontal headache, loss of appetite, digestive problems, metallic taste in the mouth, intolerance of fatty foods, malaise, postprandial drowsiness, pain in the right quadrant, and jaundice.

Silybum Marianum, or milk thistle, is a powerful liver protectant and antioxidant that has been used for more than 2,000 years as a first-line medicinal and nutritional therapy. Its flavonoid active ingredient, silymarin, stabilizes and protects the liver against poisons and toxins.

Mechanisms of action include alteration of the liver cell membrane to prevent toxin transport; disruption of toxin binding by occupation of the toxin receptor site; and inhibition of inflammatory agents. Silymarin also increases hepatocyte protein synthesis and protects against glutathione and superoxide dismutase (SOD) depletion.

Over the last 40 years, hundreds of European studies have been conducted in patients with acute or chronic liver disorders, including alcoholic cirrhosis and hepatitis A, B and C. Results have shown that silymarin treatment significantly improves liver function and tissue regrowth, and decreases mortality and recovery times.

One remarkable German study was conducted in 60 people with severe Amanita (Death Cap) poisoning (frequently fatal) who received IV silymarin treatment; not one patient died.

Also intriguing are recent U.S. studies from Case Western in which "exceptionally high to complete" protection against tumorigenesis was seen in human breast tissue and in mouse skin that had been exposed to carcinogenic levels of UVB.

In addition to patients with liver disease, people who smoke, use alcohol or drugs, eat food high in fat, or have psoriasis may benefit from milk thistle supplements. Those who work with toxic substances or live in highly polluted areas may also benefit. Even in very large doses, no toxic effects of milk thistle have been reported.

The American Botanical Society (512-331-8868) is a good source of more detailed information and references on milk thistle and other herbs.

Watch the literature on silymarin—many new studies are under way and this may only be the tip of the thistle!

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Milk Thistle: It Loves Your Liver

Milk thistle has been used since ancient times for treating every kind of liver ailment.
Drawing by Michael Fischer, San Carlos, CA

- The liver is the second largest organ in the body (the skin is the largest) and it works harder than any other organ to keep us healthy.
- Its most important job is to regulate and detoxify everything that enters the body through the lungs, digestive tract, and blood stream.
- Protection from the harmful effects of junk food, alcohol, drugs, tobacco and even medicine is as important as protection from toxic chemicals, pollutants, pesticides, and heavy metals.
- People have used milk thistle for more than 2,000 years to treat liver ailments, digestive, kidney, gallbladder and menstrual problems, psoriasis and varicose veins.
- Look for milk thistle that contains a standard extract of 80% silymarin (the active ingredient in milk thistle).
- Silymarin is a powerful antioxidant that protects and regenerates liver tissue, even in acute poisoning with “Death Cap” mushrooms and highly toxic chemicals.
- Even at a high doses, no toxic effects of milk thistle have been reported.
- Milk thistle shows promise as an antitumor and anticancer agent in skin and breast tissue.
- Ask your pharmacist to tell you about new developments in the uses of milk thistle!

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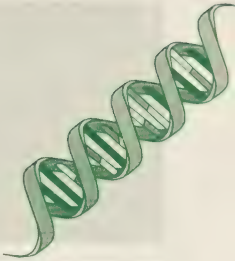

Mark you calendars!

The 1999 MPhA Mid-year Meeting

Date: Saturday, February 6 &
Sunday, February 7, 1999

Location: The Inn & Conference Center
University of Maryland University College
College Park, Maryland

Continuing Education: Saturday, Herbal Medications
Sunday, New Drugs

Other Activities: Sunday, Trade Show

School of Pharmacy Honors Achievement, Leadership and Commitment

A warm, sunny fall afternoon was the setting for the annual School of Pharmacy Honors Convocation. The event celebrated the School's long history of leadership and achievement by recognizing members of the student body who have excelled in academic and student leadership activities during the past year.

Twenty-nine upper classmen received academic awards while another 23 were recognized for outstanding achievements in student activities. Ms. Yoo Chang received the Omicron Chapter of Rho Chi Society Book Awards for outstanding scholarship. The award was presented by Dan Erhlich, President of Omicron Chapter who also serves as a national officer in Rho Chi, the honor society of pharmacy.

The Honorable Bennett Bozman, an eight-year veteran delegate to the Maryland General Assembly from Berlin, Maryland, received the 1998 Honored Alumnus Award from the School of Pharmacy Alumni Association. Mr. Bozman, a 1961 graduate of the School of Pharmacy, received the award for his career-long involvement in community activities with the volunteer fire department in Berlin culminating in several years as Chief. His involvement in local politics led to his election to the General Assembly in 1990 where he now serves as a member of the powerful House Appropriations Committee. Delegate Bozman played a significant role in negotiating the complex arrangements for a new headquarters building for the Maryland Pharmacists Association on University campus. This building will also include the new home for the Maryland Poison Center. The permanent funding for MPC was due in large part to Delegate Bozman's active support during the 1997 session of the General Assembly.

Mr. Bozman urged the students to take an active role in politics, even while they are still in school in order to influence important policy issues. He pledged his continuing support to the School of Pharmacy and its quest for state support for new buildings.

The Alumni Association received a grant from the University of Maryland Alumni Association International in support of the Pharmacy Ambassadors Program. The ambassadors are a specially-selected group of students who will represent the School to the public in a variety of ways during the coming years. They will host important dignitaries when they visit the School, serve as liaison to external groups and assist with special events such as the Honors Convocation and the Alumni Banquet. Neil Leikach, member of the Board of Trustees of the School of Pharmacy Alumni Association, received the grant award from Mr. William Snyder, representative of the Alumni Association International. Alumni scholarships were presented by Charles Sandler to eight students.

The Convocation included a white coat ceremony for members of the Class of 2002. Each student donned the symbolic white coat in front of the Convocation audience to represent his or her commitment to the ideas of the practice of the profession of pharmacy. They were assisted by the President of the Student Government Association, Melanie Ruane, and the President of the Class of 2001, Pritesh Shah. All of the pharmacy students present for the Convocation then stood and took the oath of student professionalism administered by Associate Dean Robert Beardsley. Participants plus family and friends then adjourned for a reception celebrating the achievements, leadership and commitments of all of the students of the School of Pharmacy.

✂ Cut and Photocopy

Dietary Supplements —*Before you buy*

Many patients are not aware that dietary supplements, such as herbal products, can have interactions with their prescription or OTC medications. Some significant drug-herb interacts are listed below. There is limited information regarding interactions with herbs. Patients taking chronic medicaitons should always consult with their physician before taking an herbal product. This list does not contain all possible interactions. *Herbs marked with an asterick (*) are considered too dangerous for routine use.*

If the *herb* contains:	**It may interact with:**
Alfalfa	warfarin (Coumadin®)
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Cinnabar root (*Salviae multiorrhizae*)	warfarin (Coumadin®)
Dong Quai* (*Angelica sinensis*)	warfarin (Coumadin®)
Feverfew (*Tanacetum parthenum*)	aspirin dipyridamole (Persantine®) warfarin (Coumadin®)
Garlic	aspirin dipyridamole (Persantine®) warfarin (Coumadin®)
Ginkgo biloba	aspirin dipyridamole (Persantine®) warfarin (Coumadin®)
Ginseng (*Panax* species) (American, Korean)	furosemide (Lasix®)
Genseng (*Eleutherococcus senticosus*) (Siberian)	digoxin (Lanoxin®)
Hawthorn* (*Crataegus* species)	antihypertensives heart medications
Kava kava*	alcohol sedatives

If the *herb* contains:	**It may interact with:**
Licorice*	digoxin (Lanozin®) diuretics (see below) corticosteroids (prednisone, Medrol, others)
Ma Huang*	beta blockers (see below) MAO inhibitors (Nardil, Parnate) methyldopa (Aldomet) stimulants (caffeine, decognestants) St. John's wort
Melatonin	antidepressants (see below)
Psyllium (*Plantago* species)	digoxin (Lanoxin®)
Sarsaparilla (*Smilax* speicies)	bismuth (Pepto bismol®) digoxin (Lanoxin®)
St. John's wort (Hypericum)	antidepressants (see below) dextromethorphan ephedrine lithium meperidine (Demerol®) pseudoephedrine (Sudafed®), others) selegiline (Eldepryl®) yohimbine
Yohimbine*	antidepressants (see below) anthihypertensives stimulants (caffeine, ephadrine, others) St. John's wort

Antidepressants include Elavil, Tofranil, Sinequan, Pamelor, Aventyl, Surmontil, Asendin, Norpramin, Anafranil, Luvox, Paxil, Prozac, Zoloft, Remeron, Desyrel, Wellbutrin, Serzone

Beta blockers include Inderal, Tenormin, Sectral, Lopressor, Corgard, Toprol XL, Visken, Blocadren, Zebeta, Kerlone, Betapace, Levatol, Catrol and others

Diuretics include Lasix, Diuril, Esidrix, HCTZ, Hydrodiuril, Naturetin, Enduron, Lozol, Naqua, Renese, Hydromox, Zaroxolyn, Hygroton, Bumex, Edecrin, Demadex

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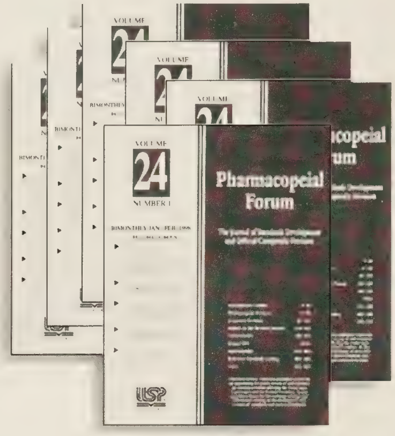

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Managed Care—℞ecord Growth

The slow and steady climb in prescription drug costs upgraded to fast and steep in 1997, according to the second annual Drug Trend Report, published in June by Express Scripts/ValueRx. And managed care will have to employ more aggressive cost-cutting measures if it expects to stay ahead of the game, according to industry watchers.

Overall, prescription drug costs rose 16.1% in 1997, according to the report—the biggest jump in years. From 1993 to 1996, average wholesale price per member per year (PMPY) increased by a total of 35%, or 8.75% per year over that four-year period—from $ 180.25 to $ 243.34 PMPY. *In 1997 PMPY costs shot up to $ 282.48.* This was thanks in large part to high-priced new drugs and changes in therapy mixes and utilization, and not necessarily to price increases by the pharmaceutical industry, in the opinion of Express Scripts/ValueRx CEO Barrett Toan.

"One of the key points we make [in the report] is that price increases, per se, have not been the major driver of the trend," Toan said. "It's not primarily the pricing of existing, or what we call 'common' drugs, that were being used five years ago. It's all these other factors: partly utilization, therapy mix, the use of stronger agents to treat the same illnesses, and the cost of new drugs that didn't exist five years ago."

As a result, some cost-cutting measures put in place by managed care organizations (MCOs) are useless, noted Mary Sevan of Sevan Associates, which consults with MCOs on pharmacy issues. "The cost is increasing not because people are using lots of brand drugs that are available generically. What's driving it is the new drugs that are more expensive, that have no generic alternatives. They just hit the market, and doctors want to try them," she said.

While the year-end figure of 16.1% growth may seem startling, Sevan said it's no surprise to the managed care industry. "They've been watching it on a month-to-month basis," she explained. "They're already trying to react to it…We're seeing more and more organizations go toward a restrictive formulary to try to get those costs under control. We're seeing things like quantity limitations…[for] a drug that may be for acute use."

One current, highly publicized example is Viagra (sildenafil, Pfizer). By allowing the drug to be used by limiting how many tablets they will pay for each month, MCOs are controlling their expenditures, Sevan explained. "It kind of reinforces the fact that we need to manage these formularies and go beyond just having a free-for-all, open season where anyone can use anthing."

Toan agreed, adding that some of the employer groups and health maintenance organizations his company works with are already seeing results from employing additional measures such as tiered co-pay programs. Many of these plans, he said, have shown just single-digit increases in drugs spending.

"From a benefit-design standpoint, the biggest single trend has been the consideration and implementation of what we call three-tier co-pay plans" in which patients and physicians can choose virtually any product in a given class, Toan said. Choosing a more expensive brand product over a generic, however, means the patient will pay more out of pocket. "I think three-tiered co-pay is seen as a way to give the employee or patient the choice of whether they want to continue with that particular therapy …as opposed to not allowing access to that drug."

Toan said MCOs may also try to get physicians to select effective older and presumably less expensive products as first-line therapy, saving their more costly high-tech counterparts for particular cases.

Obviously, not all drugs (or classes) saw comparable growth. Thyroid products experienced the biggest price jump, increasing 8.6%, with utilization growth of 10.8%. Dermatological prices did not change at all, while utilization grew at just 0.7%; corticosteroid costs dropped 15.4%, in spite of a utilization growth of 4.9%. All in all, 17 therapy classes showed an increase in utilization, while eight declined. Only three product classes showed price decreases.

Managed Care—Record Growth

(Continued from page 15)

One thing to remember, Toan noted: Changes in drug spending do not necessarily equate to changes in overall health costs. Often, he said, increases in drug costs are offsetting other components.

"A clear example would be the new AIDS drugs, which are quite successful in many cases in making [clinical improvements] in the person who is extremely sick and using a great many medical resources," he said. "Their primary use of medical expenses is the use of the drugs. What you see is fewer office visits, fewer hospitalizations and emergency room uses. The [cost savings], well managed, can be equal to or even greater than the cost of the drugs."

By Harris Fleming, Jr.
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Drug Topics, Medical Economics,
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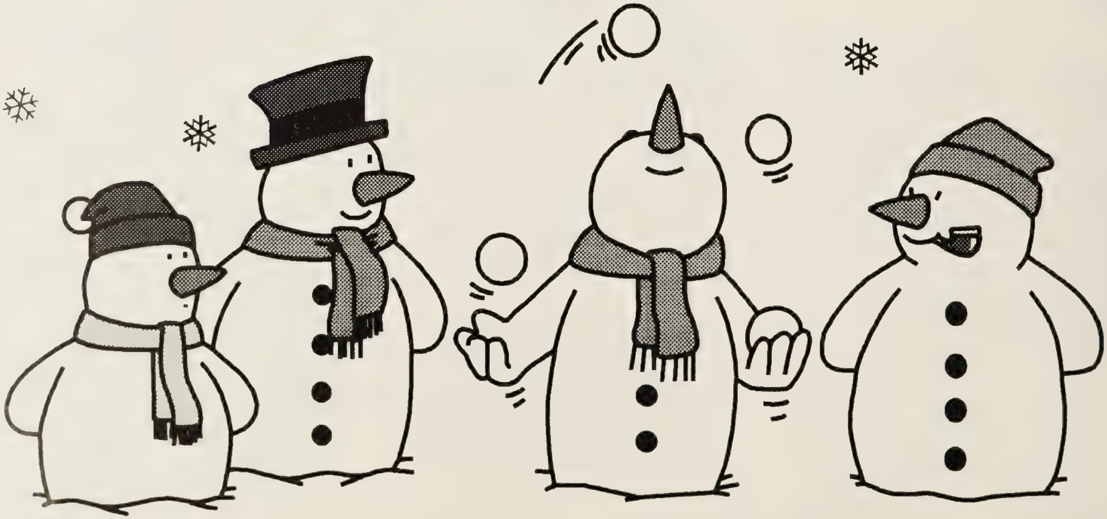

Rx AND THE LAW

By Kenneth R. Baker, B.S.Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

THE PHARMACY'S DUTY FOR REDUCING ERRORS

If a pharmacist makes a mistake on a prescription, the pharmacist may be held liable for the injuries caused by the error. Through the legal concept of vicarious liability, a pharmacy will be liable for damages caused by its employees if they are acting within the course and scope of their duties for the pharmacy. Does the pharmacy have a duty beyond this? Does the pharmacy have an independent duty to take steps to reduce errors by their employed pharmacists? According to the Alabama Supreme Court, the answer is "yes".

The Alabama case arose out of a pharmacist's mistake, which caused non-permanent injury to a patient. The patient filed a lawsuit against the pharmacy alleging the pharmacist was negligent. The patient (plaintiff) filed an additional count as part of the suit and asked for an extra monetary award to be paid by the pharmacy because it had not developed a system to assure that its pharmacists filled prescriptions correctly in the first place. The plaintiff's attorney argued that the pharmacy owed to its patients a duty to reduce the probability of prescription errors.

In the case of Harco Drugs v. Holloway[1], the pharmacist misread a Tamoxifen prescription and filled it with Tambocor. The jury found the pharmacist was negligent and that the pharmacy was responsible for the resulting injuries. The jury went further, finding the additional duty on the pharmacy as argued by the plaintiff's lawyer, and awarding the plaintiff punitive damages against the pharmacy owners.

The pharmacy appealed, but the Alabama Supreme Court agreed with the jury and upheld the punitive damages. In its decision the Court said:

> "We note that the jury was also informed of 233 incident reports that had been prepared by Harco employees during the three years preceding the

---

[1] Harco Drugs v. Holloway 669 So.2d 878 (Ala. 1995).

> incident. This evidence, in addition to evidence of complaints filed with the State Board of Pharmacy and the evidence of lawsuits filed alleging misfilled prescriptions, was relevant to show Harco's knowledge of problems, and Harco's having failed to initiate sufficient institutional controls over the manner in which prescriptions were filled."

By "institutional controls" the Court was clear that it was placing upon the pharmacy an additional duty, for which it could independently be held liable. That duty requires the pharmacy owner or chain to institute a system of risk management designed to reduce the number of errors in its pharmacies.

Several boards of pharmacy are now considering a similar position in order to stem what the boards see as an alarming rise in the number of complaints of pharmacy errors. When the number of errors reported have caused the boards to become concerned for the public's safety, some boards of pharmacy have required pharmacy owner or chains to institute a plan of quality assurance or risk management.

Risk management calls for a systematic approach to the practice of pharmacy. Human beings make errors, but a risk management system can be designed to reduce those errors. A true system of quality assurance goes beyond risk management to envelop the concept of quality measurement and continuous quality improvement. No system can eliminate errors, but pharmacy owners would be wise to begin exploring the implementation of a quality control program.

©Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorney and insurance company for specific advice. The Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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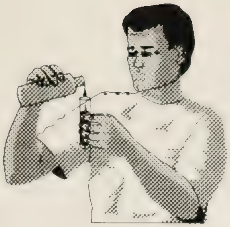

Pharm/alert® Notes

Counseling Notes for Pharmacists

Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative condition resulting from cell death in the substantia niagra. Cells gradually lose their ability to synthesize dopamine, resulting in varying degrees of motor system impairment.

Nearly a million Americans have Parkinson's disease, with about 50,000 new cases diagnosed annually. While it can occur at any age, the disease most commonly afflicts adults over 40. The causes are not known but researchers include genetic factors, physical trauma, and exposure to viral infections or toxic substances among the probable culprits.

The most common symptoms of Parkinson's disease are: 1) tremor, occurring in the hands, face, jaw, legs and arms, most noticeable when the patient is at rest (this is usually the first symptom); rigidity or stiffness when the arms, legs or neck are moved; 3) bradykinesia, or slowed movements, and difficulty in performing daily tasks, particularly those requiring fine finger movements; and 4) postural disturbances, such as impaired balance, stooping, decreased coordination, shuffling, or falling. Other symptoms include urinary or bowel difficulties, postural hypotension, problems with chewing or swallowing, sleep disturbances, and memory impairment.

Because no diagnostic tests for Parkinson's disease exist, accurate diagnosis requires a physician with specific experience in treating the condition, usually a neurologist who specializes in movement-disorders.

Patients report that symptoms associated with slowed movements are more frustrating than tremor, since the former problem causes difficulty dressing, handling eating utensils, rising from a chair, getting out of the car, turning over in bed, and taking care of normal personal hygiene. However, not all patients are affected equally—some are only slightly disabled, while others face 20 to 30 years of severe, multiple motor function impairment. Without treatment, pronounced disability occurs within about 10 years.

Medication can provide dramatic relief from the symptoms of Parkinson's disease. Drug treatment is focused on replacing the supply of dopamine to the brain. Most common treatments include levodopa (L-dopa); MAO-B inhibitors, and dopamine agonists. Anticholinergics and antiviral drugs are also used in varying combinations to stave off the use of L-dopa until it is most needed. All of these drugs cause side effects, which range from nausea, vomiting, insomnia, edema, confusion and depression to rapid tolerance, hallucinations, paranoia, dyskinesia, on-off effects and nightmares.

Regardless of the intervention used, Parkinson's patients benefit from good nutrition and regular exercise. A well balanced diet is important in maintaining general health and strength. And many patients have reported that exercise, especially swimming or walking, helps maintain muscle tone and strength. Full range-of-motion exercise also improves balance, walking and overall strength.

For more information about Parkinson's disease, contact the National Parkinson Foundation, Inc. at 800-327-4545, the United Parkinson Foundation at 312-733-1893, and/or the American Academy of Neurology at 651-695-1940.

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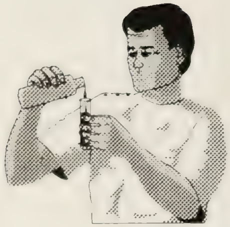

Pharm/alert® Notes

Health Tips for Patients

About Parkinson's

Parkinson's disease was named after the physician who first described it in 1817 as "the shaking palsy." It belongs to a group of neurological conditions called motor-system disorders.

- About one million Americans have Parkinson's disease, which most often occurs in adults over 40.
- Four primary symptoms of Parkinson's are:
  - tremor or trembling in hands, arms, legs, jaw and face
  - rigidity or stiffness of the limbs and trunk
  - slowed movement (also called bradykinesia)
  - impaired balance and decreased coordination
- The cause is mystery, but scientists speculate that certain genetic, viral and even environmental factors may be involved.
- The disease is chronic, in that it persists over a long period of time, and progressive, since symptoms grow worse over time.
- There are no diagnostic tests for Parkinson's disease, so it is important that patients be examined by a qualified doctor, such as a neurologist who specializes in movement disorders.
- Medication can provide dramatic symptomatic relief.
- People with Parkinson's have said that exercise, especially swimming or walking, helps maintain muscle tone and strength—and it improves their overall mobility.
- Moderate exercise and stretching of the entire body, including exercising the full range-of-motion of all limbs can improve balance, walking and strength.

For more information about Parkinson's disease
...Ask your pharmacist!

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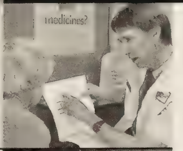

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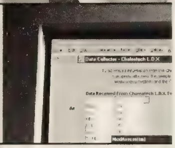

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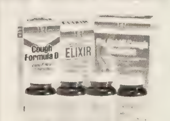

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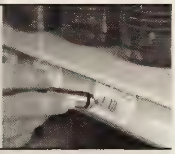

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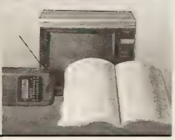

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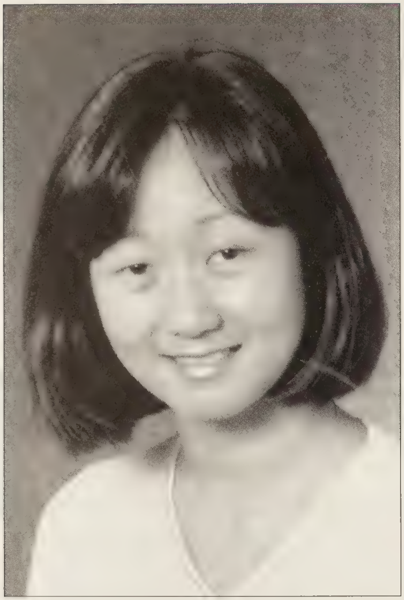

LAURA A. GOVERNALE

A student at the University of Maryland at Baltimore School of Pharmacy, for being selected to participate in the 1998 SmithKline Beecham Summer Internship program.

Laura A. Governale was one of four pharmacy students chosen to participate in this 12-week industry summer internship program. This is the 25th year that SmithKline Beecham has offered an annual summer internship program for pharmacy students. During that time, over 70 students have spent their summers working and learning in Philadelphia. Pharmacy students are selected for the program based on their applications, achievements, and faculty recommendations.

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The Schering Report XX

Schering XX: America's Largest, Fastest Growing Minority—The Elderly—Increasingly Depend on Pharmacist Guidance

The vital importance of the pharmacist in meeting the medication needs of America's largest and fastest growing minority— the elderly has been underscored by a new study. Commissioned by Schering Laboratories, the independent study showed that seniors prefer to patronize those drug stores in which the pharmacist actively guides them in using prescribed medications.

More than 5,000 adults were interviewed to obtain a representative sample of persons over and under 60 years of age. Over 80% of interviewees of all ages said the pharmacist's performance is an extremely important factor when they choose a drug store. Their top three considerations:

1. The pharmacist is knowledgeable and up-to-date about prescriptions.
2. The pharmacist has earned their trust.
3. The pharmacist makes sure they understand instructions for using the medicine.

The study found that pharmacists reciprocate the high regard of the elderly, who are among their best customers. Pharmacists commented, in passing, that the elderly are far more tolerant than younger adults with respect to delays in having their prescriptions filled. And although the elderly's incomes are about 38% lower, their out-of-pocket spending for prescription and non-prescription drugs is almost twice the average for all customers. Quoted in the study is the U.S. Consumer Expenditure Survey, which reveals that over-65 households spent $545 for drugs in the most recent year. That's 94% greater than the $280 per household paid by the entire population.

The study, Schering Report XX, is the latest in a series of annual investigations of issues and trends that impact on pharmacy. Dr. Jack Robbins, Consultant for Pharmacy Affairs at Schering Laboratories and originator of the series, pointed out that the number of Americans over 65 years of age has increased eleven fold since the 20th century began—from 3.1 million to 33 million, while the nation's population as a whole has only tripled. "By the year 2000, seniors will number 35 million. By 2010, there will be 40 million people over 65 years of age," he said. The most rapidly increasing age group within the elderly population today is the 'oldest old'. These Americans of 85 years and above already number three million. By the year 2010, the 'oldest old' population will grow to nearly 20 million.

"While the health of older Americans is better than ever, many reaching these advanced ages will experience chronic, disabling illnesses that will increase their need for medical care and assistance in daily living."

To help pharmacists meet the special needs of the elderly, Schering Report XX surveyed the health needs, practices, and preferences of Americans over 60 years of age. It focused on the role that pharmacists and pharmaceuticals play in the lives of this age group. Those interviewed were dwelling in the community, not in institutions such as nursing homes or chronic care hospitals. About 8 out of 10 of them (79%) assessed their health as good to excellent, 14% as fair, and 6% as poor.

By 2010, there will be 40 million people over 65...and nearly 20 million 85 years old or older

The Schering survey found that seniors contact their physicians more than twice as often as younger people and are hospitalized more than three times as often. It was not surprising, therefore, to discover that the elderly had an average of 4.2 prescriptions filled in the previous six months, almost twice the 2.5 prescriptions filled for younger adults. Three out of four of these prescriptions for elders were refills, compared with about half for people under 60 years of age.

The elderly's use of vitamins, nonprescription drugs, and home remedies was found to contrast sharply with their prescription-use pattern. That is, they take these products, but less frequently than younger adults do; this finding contradicts the widespread belief that the elderly are in a pill-popping frenzy.

While more than half of elderly use vitamins and over-the-counter medications, only a fifth use home remedies such as herbs and other natural substances, according to the survey. They visit chiropractors on a par with younger adults, but are less likely to use holistic medicines based largely on spiritual beliefs. Almost none has tried acupuncture.

The elderly, it was discovered, use a wide range of drug stores, but the types patronized most frequently are chain store pharmacies (40%) and independent pharmacies (25%). In the performance of pharmacists, patrons of independent pharmacies reported the greatest overall satisfaction.

Compared to younger adults under 60 years of age, seniors are more likely to use an independent pharmacy (25% vs. 19%) and less likely to patronize a chain store pharmacy (40% to 48%), the researchers found.

Just over half of the seniors interviewed have a prescription insurance plan, compared with over two-thirds of younger adults, many of whom have employer-paid insurance. Twice as many seniors (16% vs. 8%) are enrolled in Medicaid.

Half of the elderly patients in the survey said they value their personal relationship with pharmacists. The importance patients placed on pharmacist-related matters did not mean that other subjects were deemed unimportant: for example, such considerations as store location, hours of operation, prompt service and low prices were mentioned by over 70% of older and younger adults queried. Other reasons for selecting a particular pharmacy were: required by the insurance plan, discounts given, and availability of delivery.

The study pointed out that, among seniors, females attach significantly more importance to just about all of the reasons for selecting a pharmacy than do males. Conjecturing on some possible explanations, the study said: "One reason may be women's greater experience in buying necessities for the household. Throughout their adult lives, most have served as the primary shopper. Another likely explanation is that they are the principal and sometimes the only caregivers in the family."

"In addition to fulfilling these household roles, women are much more watchful regarding their own health. Over a lifetime they consult their physicians about 50% more often than do men."

Schering Report XX observed that many patients of all ages had problems - real or perceived - in having their prescriptions filled. "These shortfalls range from frequent long waits to the uncommon but potentially hazardous problem of prescription error," it noted. In this connection, the report pointed to a widespread notion fostered by television and movies, that seniors are more cantankerous than younger people. Shattering that stereotype, the study found that seniors were far more patient when encountering the same problems as younger patients. "There was only one exception" the report noted, "namely, the high cost of the prescription. This was the chief gripe of seniors and the number two grievance of the younger age group. "Otherwise, seniors reported on average only half as many annoyances as did younger people with those using independent pharmacies reporting the fewest problems overall.

Concerning pharmacists' counseling of patients, the report observed that this has become a legally mandated requirement in nearly all states during the past decade. In addition, a national program enacted in 1997 - the Medguide action plan - requires that comprehensive written information must be provided to 75% of new prescription patients by the year 2000 and 95% by 2006.

On this point, the report stated: "Our survey revealed two encouraging developments: first, the year 2000 goal may have already been met; and second, pharmacists are talking more with patients about the proper use of their medicine."

Back in 1991, the then-current Schering Report found that, at most, 25% of patients could recall discussing with a pharmacist such matters as how often, how much, and how long to take their medications. In 1994, a survey by the National Association of Boards of Pharmacy showed that only 38% of patients even got an offer of counseling, and that a scant 27% said they actually had a discussion about their prescriptions with anyone at the pharmacy. In contrast, Schering Report XX found almost three-quarters of patients recalling a discussion with the pharmacy staff on how to use their most recent prescription.

However, when researchers for the current Report examined the levels of verbal counseling, they came to the conclusion that seniors were getting "less than their fair share."

"To their credit," Schering Report XX said, "pharmacists personally counseled 8 of 10 patients, young or old, compared with the barely half we found in earlier years. Talking with the pharmacist, rather than a clerk or cashier, has major benefits for the pharmacy as well as patients. Seniors who talked with the pharmacist received advice that was more authoritative than those who spoke with a clerk or cashier. And they received more advice - that is, an average of 4.9 topics was discussed with the pharmacist, compared with 3.9 topics discussed with other pharmacy staff."

"The critical question is how many patients received information about their medication, either from one source or another. The answer: an overwhelming 9 out of 10. Furthermore, more than half of the patients received information from both (verbal and written) sources."

With respect to counseling, characteristics which distinguish one type of pharmacy from another were noted as follows:

Independent pharmacy: Patients of independent drug stores were more likely to have received verbal counseling (79%) than those who patronized other types of pharmacies, and to have received counseling from the pharmacist (87%). Independent pharmacy patrons were also more likely to have discussed whether or not the prescription should be refilled (57%). On the other hand, these patients were far less likely to have received written information (61%).

> ***...50% of seniors feel that 'knowing me and my family' is an important reason to choose a pharmacy...***

Chainstore pharmacy: Patients of chain drug stores were less likely than other patients (with the exception of mail order users) to have received verbal counseling (69%).

Supermarket/department store pharmacy: Patients who purchased prescriptions at these operations were more likely than other patients to have received written instructions with their medication (85%).

HMO/hospital pharmacies: Patients of these establishments were more likely than other patients to have discussed the precautions to take while using the medication with someone other than the pharmacist (28%).

Researchers unearthed an aspect of compliance which, to their knowledge, has never heretofore been reported. Although most patients say they try to be compliant (94% of the younger adults and 95% of the seniors follow the directions on their medications either "completely" or "pretty much"), it is the seniors who actually achieve the highest level of compliance (87% vs. 80% for younger adults).

Summarizing the major message of Schering Report XX, Dr. Robbins had this to say: "Counseling by the pharmacist may well be the way for drug store operators to create strong, lasting relationships with all Americans, seniors and juniors alike. The key role of the pharmacist suggests that the filling of a prescription and the counseling of patients is a deeply personal encounter that fulfills human needs on ascending levels, the physiological need to sustain or recover health, the need for safety and security in using the medication, and the social need for recognition by the pharmacist as an individual, validated by the person-to-person communication.

Talking with the pharmacy cashier or receiving a sheet of instructions falls far short of patients' expectations of high quality, personalized service from a trusted counselor. Satisfaction of this hierarchy of needs may be the motivation that causes seniors - beginning about age 50 - to shift their patronage from big and busy chain pharmacies to smaller independent pharmacies where they are more recognized as individuals. Recall that 50% of seniors feel that 'knowing me and my family' is an extremely or very important reason to choose one pharmacy rather than another."

You can get a free copy of Schering Report XX by writing to Jack Robbins, Ph.D., Consultant, Pharmacy Affairs, Schering Laboratories, 2000 Galloping Hill Road, Kenilworth, NJ 07033.

Summerized by Tennessee Pharmacist Association, Sept. 1998

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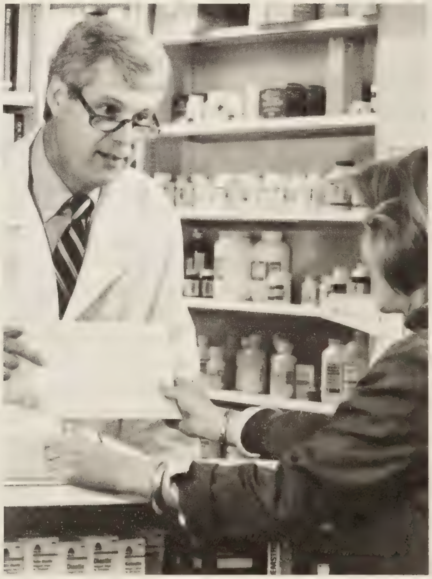

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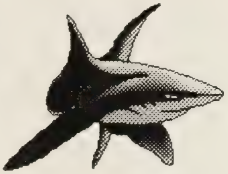
Pretty Fishy, Pretty Profitable: Shark Cartilage Update



Whether or not it is an effective therapy for cancer, rheumatoid or osteoarthritis, or immune function, shark cartilage sells. Over 50,000 patients worldwide have taken shark cartilage for one reason or another over the past five years, and no adverse immune binding or allergic reactions have been reported in the literature.[1] One brand alone, BioTherapies' Cartilade™, claims that its product has been safe and effective in over 300 million doses worldwide. And the National Cancer Institute (NCI), in conjunction with the National Institutes of Health (NIH) Office of Alternative Medicine (OAM), was interested enough in shark cartilage this year to initiate clinical trials to investigate its efficacy and safety in patients with a variety of advanced cancers. Meanwhile, another manufacturer—Lane Labs-USA, Inc., Allendale, New Jersey—is involved in FDA Phase II clinical studies of shark cartilage for advanced breast and brain cancer. Northwestern University, Chicago, Illinois (an NCI accredited research facility), is testing the company's BeneFin™ shark cartilage product on patients with advanced forms of brain cancer. Other studies are being conducted on the effectiveness of BeneFin™ on early stage and late stage prostate cancer, and it is also being considered for "Orphan Drug Status" by the Food and Drug Administration (FDA)—which means that if successful, the product could be approved for certain forms of brain cancer that affect less than 200,000 people in the U.S.

Questions Remain

Practitioners, patients, and pharmacists all report, however, that there are still mixed opinions and mixed results. Enrico Liva, R.Ph., N.D., Connecticut Center for Health, Middletown, Connecticut, says, "I was generally turned off to shark cartilage because of the lack of clinical evidence showing efficacy regarding the dose needed (60-100 g daily or 3-5 tablespoons four times a day). When a friend of mine published data showing me some efficacy used with a more comprehensive nutritional program, I treated patients with a dose of 60-80 g of cartilage daily in patients with ovarian cancer, lung cancer, and prostate cancer. The ovarian and lung cancer patients have passed away, but the prostate cancer patient who had radiation seed implanted dropped his cartilage dose to 8-10 g daily and continues to do very well. Another of my colleagues also treated patients with cartilage with no good results."

There is no consensus on doses for shark cartilage. While one manufacturer recommends an ideal starting dose of 1 g of shark cartilage per kilogram (2.2 lbs.) of body weight, others recommend far smaller doses.[2]

Sorting Out the Controversy

New York City chiropractor Howard Benedikt, M.S., D.C., prescribes shark cartilage for sports conditions. "Shark cartilage has been shown to be a potent, nontoxic, antiinflammatory agent due to the presence of mucopolysaccharides, chondroitin sulfates A and C found in shark cartilage," say Benedikt. "Numerous double-blind studies have shown that chondroitins yield equal to better results than NSAIDs. Two studies have failed to show any toxicity in the use of shark cartilage. Therefore, it appears to be an appropriate therapy for treating not only traumatic sports injuries, but also other types of chronic degenerative joint conditions and soft tissue injury. At the same time, it appears to aid the return of athletes to competition sooner than aspirin. Further studies need to be done to evaluate the mechanism of action of shark cartilage."

Best Results

Yet Benedikt still has some reservations. "I've found the best results in the management of tendonitits, bursitis, and lower back and knee pain," say Benedikt. "I've also seen that most forms of osteoarthritis (DJD) as well as rheumatoid and gouty arthritis respond favorably to it. But I've had mixed results using shark cartilage to treat non-specific joint pain and inflammation involving no-weight bearing joints."

Nutritionist and women's health authority Shari Lieberman, Ph.D., C.N.S., also reports mixed results. "I haven't seen any good studies linking arthritis and shark cartilage, and it doesn't work better than glucosamine," say Lieberman. "As for cancer, BeneFin™ was the shark cartilage product used in the cancer studies, so when I do prescribe shark cartilage, that's the brand I recommend."

Pharmacists Respond

How do the pharmacists who fill the requests of customers and the prescriptions of practitioners feel? Steve Litvak, Santa Monica Homeopathic Pharmacy, Santa Monica, California, complains that most companies don't process shark cartilage properly. "A lot of products are bleached, which ruins 50% of their therapeutic activity," says Litvak. "The chlorine in the bleach can also make the products toxic." Litvak adds that origin is important, so he uses the products on which key shark cartilage studies have been based, such as BeneFin™. He also cautions fellow pharmacists to get laboratory assays of shark cartilage brands before stocking them.

Susan Corviea, R.Ph., CVS Pharmacy, Bronxville, New York, says her customers haven't asked her for shark cartilage products even though she does stock them, adding, "We don't recommend anything that isn't FDA approved." (Note: Shark cartilage was granted IND status by the FDA in 1995.)

Mike Rodgers, R.Ph., Natural Pharmacy, Asheville, North Carolina, only carries the Solgar brand of shark cartilage because of the company's reputation for quality. He admits, however, that, "it doesn't do well for us. We have a few patients who use shark cartilage to treat their arthritis, but we don't recommend it since glucosamine and chondroitin sulfate work so much better for arthritic conditions such as osteoarthritis. And shark cartilage is so much more expensive than glucosamine and chondroitin sulfate."

Getting Results

More important is whether shark cartilage actually helps customers recover. Litvak say it can help treat some conditions if enough is taken, but that would mean taking 45-60 g daily for a serious condition such as cancer. Benedikt adds that other factors must be considered as well when recommending a shark cartilage dose, including the patient's age and overall health and the functioning of his or her digestive system.

Pharmacists are also divided about which brands to recommend. Tom Cremona, R.Ph., Professional Pharmacy, South Norwalk, Connecticut, favors cartilage and cartilage/chondroitin products from companies such as Advanced Nutritional Technology, Cartilage USA, Inc., Olympian Labs, Inc. and Solgar Vitamin and Herb Company. Yet he too has mixed feelings. "While shark cartilage is being used more and more for cancer, I haven't seen enough data to be convinced. I recommend taking it with IP-6 (See "Supplement Snapshot" in the August 1998 *Natural Pharmacy*). But even then there are problems. In this form, only 8% of the chondroitin is absorbed. And while shark cartilage has merit in high doses, it's problematic in terms of intake and cost."

Manufacturers Speak Out

According to Andy Lane, President of Lane Labs, manufacturer of BeneFin™, which claims to have 99% of the shark cartilage market share, "Our product is processed to be a clinical pharmaceutical grade product, so it goes well beyond not being bleached. The BeneFin™ sold now is actually a second-generation product that is demonstrably different than the one on shelves five years ago."

Not all shark cartilage manufacturers believe that their product is useful for cancer. BioTherapies, Inc., which manufactures Cartilade™, which it calls "the world's best selling brand of shark cartilage" as well as "simply the best clinically proven brand of shark cartilage," insists that "the jury remains out on any benefit of shark cartilage in cancer." What it does believe, which Michael Schacter, M.D. supports, is that shark and bovine cartilage may work synergistically. BioTherapies is currently promoting bovine cartilage, which it claims is eight times more potent than shark cartilage, for use with cancer patients.

The Shark Sales Tales

While more than 60 brands of shark cartilage have been introduced over the past half decade, not all have stood the test of time and the marketplace.

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973-808-1400

Cartilage USA, Inc.:
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Lane Labs:
201-236-9090

Olympian Labs, Inc.:
800-473-5883/602-483-2302

Solgar Vitamin and Herb Company, Inc.:
201-944-2311

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1. *Townsend Letter for Doctors and Patients*, October 1997
2. Sorting out the cartilage controversy. Nutrition Science News web site (www.nutritionscience-news.com), July 1998.

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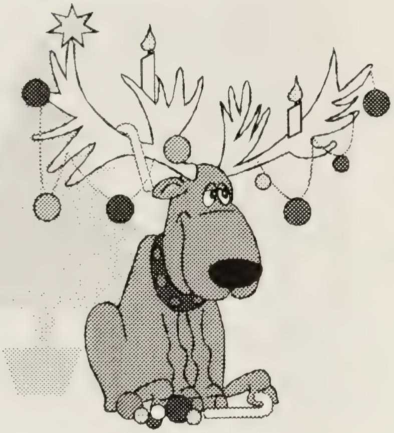

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Continuing Education for Pharmacists

Volume XV, No. 4

Patient Counseling: Sleep and Insomnia, Part 1

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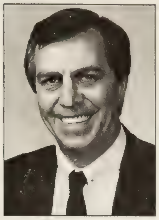
Goals. The goals of this lesson are to explain the physiology of sleep, discuss insomnia, and provide information to counsel patients effectively.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. differentiate between the terms NREM, REM, delta sleep, and slow-wave sleep; and identify events associated with sleep stages 1, 2, 3, and 4;
2. choose the neurotransmitters involved in sleep physiology and state their proposed activity in promoting or opposing sleep;
3. demonstrate an understanding of the cause, classification, and management of insomnia; and,
4. select from a list, counseling points to convey to patients who express concern about their sleep patterns.

Gossel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Individuals differ widely in their average sleep times. Newborns need 16 to 18 hours per day, children to age 10 need approximately nine to 10 hours. Adolescents require about eight hours, while older adults sleep about 6.5 hours per night.

Approximately five to six percent of women over age 40, and seven to nine percent of men in their seventies and beyond are reported to use hypnotics or other psychotherapeutic agents to induce sleep. Most say they use them only for short periods of time, usually between one day to two weeks at a time. In one study, 11 percent of patients surveyed reported using the drugs regularly for a year or more. As many as five percent or more of Americans use nonprescription sleep aid products, including melatonin.

There is a need for improved public awareness of and education about sleep disorders. Patient complaints about difficulty in sleeping, especially if they persist, should be taken seriously and treated appropriately. Troubled sleep can worsen other illnesses and cause frustration and depression.

Physiology of Sleep

The brain stem selectively limits sensory input upward to the cerebral cortex during sleep. Sleep provides a temporary period of loss of consciousness in order for the brain and body to recover from one day's activity and prepare for the next.

The amount of sleep received the previous night can affect a person's alertness the next day. Excessive sleep can also cause mental sluggishness the following day. This is explained partly in that the brain remains active during sleep. Dreaming plays an important role in restorative activities. Following sleep, individuals are set to take on and process new information the next day.

Bizarre behavior and temporary neurosis and/or psychosis can follow sleep deprivation. With four to five days of deprivation, the body's energy is depressed. Blood levels of adrenocorticoids are elevated, and substances similar in structure to serotonin and LSD appear. Memory fails, normal mental acuity is impaired, and attention span is severely limited. Hallucinations may occur, and reality may eventually merge into a continuum from which sleep is the only release.

Disturbed sleep at night with resulting sluggishness during the day is a primary contributor to work-related accidents and lost productivity. It is reported that up to 200,000 automobile accidents are caused each year by drivers who fall asleep at the wheel.

Maintenance of the immune system is believed to promote regeneration of immune processes. Endogenous chemicals have been discovered that promote sleep and play a role in the healing process. One substance, factor S, stimulates production and release of interleukin-1 which contributes to the body's defense against disease. Sleep may eventually be categorized officially as a component of the infection-fighting mechanism since the immune response seems to be so dependent on adequate amounts of it.

The adverse effects associated with sleep deprivation can be explained by summarizing events that are thought to occur during stages 3 and 4 of non-rapid eye movement (NREM) sleep, and rapid eye movement (REM) sleep. Sleep stages will be discussed in greater detail shortly. Stages 3 and 4 of NREM sleep are believed to provide the body with a period during which it can restore cellular activity. Accordingly, biologic processes are restored and the depressed metabolic rate that occurs during this time may allow for conservation of energy. Growth hormone secretion is increased during stage 3 and 4 of NREM sleep, especially in children and adolescents.

REM sleep is also important. There is increased protein synthesis within the CNS throughout the REM sleep period. Depleted neurotransmitter levels, which are responsible for thought and other CNS activities, are also restored. This may be the physiologic purpose for dreaming.

There is evidence that REM sleep is required for discarding unusable information collected during the previous period of wakefulness, and for cataloging and maintaining memory, emotional balance and mood stability. Dreaming may be a means by which the brain integrates old and new input into new patterns, allowing for psychic growth and personality development. Creative thinking may also take place during REM sleep.

Neurotransmitters and Sleep. Hypnotic drugs modify acetylcholine, dopamine, GABA and/or serotonin activity. Thus, much research effort is directed toward gaining an understanding of what contribution each neurotransmitter plays in the sleep process.

Acetylcholine is a major stimulus for alertness and memory. Acetylcholine also helps initiate and maintain REM sleep.

Dopamine can be either inhibitory or stimulatory, depending on the site of action in the brain, the subtype of receptor innervated, and its concentration. Dopamine increases blood pressure and muscular activity, and stimulates the thought process. It is also considered to be the "reward" and "pleasant thought" neurotransmitter.

Gamma aminobutyric acid (GABA) is an inhibitory neurotransmitter. GABA is considered to be the most important inhibitory neurotransmitter in the upper brain stem where sleep is regulated, and in the foreparts of the higher centers of the brain. **Serotonin** also plays a role in sleep. Serotonin exerts an inhibitory action that opposes the stimulatory effects of dopamine. Serotonin is important in the late stages of NREM sleep which is controlled in the brain stem.

Table 1
Comparison of REM and NREM Sleep

	REM	**NREM**
Brain waves	mixed, frequently	slow, delta
Muscle movement	absent	present, but slow
Eye movement	rapid	absent
Autonomic nervous system	variable	regular
Control of respiration	altered	same as awake

Electrophysiologic Considerations

In a recording process termed polysomnography, electrophysiologic instruments are used for the observation and measurement of sleep. These devices include the electroencephalogram (EEG) to measure brain activity, the electrooculogram (EOG) to determine eye movement, and the electromyogram (EMG) to monitor muscle movement in the jaw. The minimal recordings necessary for adequately scoring sleep stages are two EOGs, one EEG, and one EMG.

Sleep Stages. Sleep is categorized as NREM and REM (Table 1). NREM sleep is subdivided further into stages 1 through 4.

Periods of wakefulness as recorded on a polysomnograph are characterized by rapid EEG tracings, enhanced muscle tone, and various rapid movements of the eye that include blinking. Periods of NREM and REM sleep occur alternately throughout the night.

During stage 1, polysomnograph readings show low level EEG activity, slightly decreased muscle tone, and slow, rolling eye movements. Some experience it as wakefulness and others as drowsiness, since stage 1 is a transition phase between wakefulness and sleep.

A drifting or floating sensation may be experienced during stage 2. If awakened during this period, the person will often deny being asleep, responding that he was "... just resting my eyes." Stage 2 sleep is the first period of real sleep because reaction to non-irritating

Table 2
Major Causes of Insomnia

Medical
Pain
Itching
Nocturia
Inflammatory bowel disease
Cardiovascular disorders
Neoplasms
Infections
Endocrinologic & metabolic disorders
Fever
Chronic obstructive pulmonary disease

Psychologic/Psychiatric
Alcoholism
Anxiety
Depression
Excitement
Mania
Panic disorder
Schizophrenia
Serious illness
Stress
Worry

Other
Disruption of circadian rhythms
New sleeping environment
Drugs (e.g., alcohol, nicotine, theophylline, sympathomimetic amines, caffeine, thyroid, steroids, antihypertensives)
Drug dependence/withdrawal
Sleep apnea
Periodic limb movements

external stimuli is lost. Approximately one-half of total sleep time occurs at this level.

During stages 3 and 4, heart rate and respirations slow and muscles relax. Individuals do not respond well to external stimulation and are hard to awaken. Brain activity increases, being internalized rather than responding to external stimuli. Stages 2 and 3 together are often referred to as delta sleep, which is the deep, restorative sleep that most people describe as truly restful. Delta sleep is also believed to be significant for the immune system to function effectively. Stages 3 and 4 collectively are termed slow-wave sleep, because of the characteristic EEG pattern. There are few eye movements in NREM sleep. Patients deprived of delta sleep experience impaired daytime alertness and performance.

EEG recordings that are similar to that seen in stage 1 characterize REM sleep, but there is decreased muscle tone and bursts of rapid movement in both eyes. Dreaming occurs during REM sleep. The high brain activity and rapid eye movement denote that the individual is observing events he perceives are happening. The decreased muscle tone may actually function to protect the person from acting out these dreams.

Sleep Cycle. Sleep occurs in a cyclical pattern. Young adults move quickly from being awake through stages 1 and 2, then spend a moderate amount of time in delta sleep. Approximately 90 minutes after onset of sleep, they enter the first REM episode which may last only five to seven minutes. This cycle is repeated four to five times each night at 70- to 90-minute intervals.

During the night, less time is spent in delta sleep while REM periods lengthen and intensify. The final REM period of the night may last up to 60 minutes. On average, people spend about 75 percent of the night in NREM sleep, with the remainder in REM sleep.

The elderly spend considerably less time in delta sleep. Their level of sleep is lighter with increased awakenings during the night, though they nap more during the day. Thus it is unclear how much daytime napping and specific sleep pathology, such as sleep apnea and periodic limb movements, contribute to the decrease in night sleep in the elderly.

Insomnia

Insomnia, an inability to sleep, is the most common of all sleep disturbances. Sufferers often become anxious and tense as they approach bedtime. They may worry about work, health, and other personal problems or dwell on how much sleep they might get that night. In the morning, they will feel anxious, sleepy, depressed, worried and irritable.

Etiology. The biochemical and pathophysiologic reasons for insomnia are uncertain. The balance in concentration of the sleep-controlling neurotransmitters listed earlier is extremely important. Table 2 lists representative causes of insomnia.

Pain and irritation may cause difficulty falling asleep, and result in increased nighttime awakenings and lighter sleep. Nocturia (excessive urination at night) may be a medical reason for insomnia or the result of taking a diuretic too late in the day. Serious psychiatric disorders such as schizophrenia, major depression, and mania will cause sleep disturbance. Insomnia associated with emotional upset is also common.

Nineteen specific mental, neurologic, and medical disorders that are associated with sleep disturbances have been identified. Additional causes include disruption of circadian rhythms such as jet lag or work shift change, change of environment including sleeping away from home, sleep apnea, periodic limb movements, use of stimulant drugs, drug dependence, and drug withdrawal.

Classification of Insomnia

Insomnia is classified as acute (transient), short-term, or chronic (long-term or persistent). Transient insomnia occurs in individuals with otherwise normal sleep patterns. It usually does not persist beyond several days and is associated with acute stress or disruption of the person's biologic clock. Hypnotic drug therapy may or may not be indicated.

Short-term insomnia is similar to acute insomnia except that it persists for up to four weeks. It is associated with situational stress such as loss of a loved one, but it can also be due to a serious medical illness. Patients with this form of insomnia often respond to sleep hygiene measures listed in Table 3.

Chronic insomnia lasts longer

than four weeks, and accounts for six to 10 percent of all cases of insomnia. Patients usually have medical or psychiatric conditions, or a history of alcohol or chemical abuse. Treatment of the underlying cause is paramount.

Ten to 15 percent of patients with chronic insomnia have a history of an underlying problem with substance abuse, especially stimulants, or alcohol or other sedatives. Stimulant drugs including caffeine can disrupt sleep, especially if taken late in the day. CNS depressants can cause dependence, and, upon withdrawal, disturbed, restless sleep.

Alcohol can disturb sleep patterns throughout the night. While it may cause some individuals to feel more relaxed and able to fall asleep, the short duration of action of alcohol may actually induce mild withdrawal during the night. The person may experience disrupted sleep and increased dreaming due to REM rebound. Alcohol suppresses REM sleep early in the night. As its effect wears off, there is a tendency to recapture the lost REM sleep later in the night. The person may feel tired for the rest of the following day.

Moreover, alcohol can worsen sleep-related breathing disorders such as sleep apnea. The mechanism is to decrease muscle tone in the upper airways, which results in airway obstruction, hypoxemia (reduced oxygen concentration in the blood), hypercapnia (excessive carbon dioxide in the blood), and fragmented sleep. Recovering alcoholics may experience disturbed sleep for months or years. It is unwise to treat them with benzodiazepines or barbiturates since they may be cross-tolerant with alcohol.

Psychophysiologic insomnia can also be acute, short-term, or chronic. This is a form of conditioned or learned insomnia which the person has associated with his own bed, bedroom, or sleep process. The harder the patient attempts to fall asleep, the more difficult it is to do so. The patient dwells on his inability to sleep and the resultant daytime impairment. Persons with psychophysiologic insomnia often sleep remarkably well in the sleep laboratory, in a strange hotel room, darkened theater, and other locations removed from the causes of insomnia, or at times when they are not concentrating on trying to fall asleep. This may be the reason these individuals easily fall asleep while reading or watching television.

Management of Insomnia

Successful management of insomnia is dependent on several principles. Insomniacs must maintain a close professional relationship with their physician to help prevent misuse of hypnotic drugs and alcohol. The same reasoning holds for maintaining a sound relationship between the individual and pharmacist. When insomnia is occasional and short-term, it can often be managed successfully with an OTC product.

Additional therapeutic measures include withdrawal of excessive, inappropriate, or ineffective medications. Patients and their bed partner should be educated about sleep and the management of stress. They should be advised about supervised treatment with hypnotic agents if appropriate. Advice concerning constructive changes in the patient's coping mechanisms, personal relationships, and lifestyle is appropriate.

Patients who have psychiatric disorders, such as major depression, require treatment of their underlying disease. They may require referral to a sleep-disorder specialist if a physical cause such as sleep apnea, restless-legs syndrome, or nocturnal myoclonus (muscle contractions) is suspected, or if the patient has a particularly intractable, treatment-resistant form of insomnia.

Table 3
Suggestions for Improving Sleep Hygiene

- Do not take naps during the day.
- Determine your optimal sleep time for maximal efficiency during the day.
- Maintain regular times to retire and arise each morning. Your time in bed should not exceed eight hours each night, especially if you are elderly.
- Avoid ingesting caffeine later than mid-afternoon and nicotine before bedtime and during the night.
- Do not consume alcoholic beverages, and do not ingest large quantities of any liquid late in the evening.
- Avoid eating heavy meals or spicy foods within several hours of going to bed.
- Exercise regularly, preferably six hours before bedtime, but avoid exercise within three hours of bedtime.
- Establish a relaxing routine in preparation for sleeping. Avoid frustrating activities just before bedtime.
- Avoid using the bedroom for non-sleep activities such as watching television.
- If you are unable to fall asleep within 20 or 30 minutes, get up and go to another room. Do not return to the bedroom until you are sleepy.
- Keep the room temperature slightly cool and minimize environmental noise.

Overview

Many individuals experience temporary insomnia. When it persists or interferes with normal daytime activities, nonpharmacologic measures, hypnotics or OTC products may alleviate the problem.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Sleep and Insomnia, Part 1." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 4/15/00. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-97-004-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council and the Ohio Pharmacists Foundation are both approved providers of continuing pharmaceutical education for pharmacists by the American Council on Pharmaceutical Education.

1. The portion of the brain that selectively limits sensory input during sleep is the:
   a. brain stem.
   b. cerebral cortex.
   c. hippocampus.
   d. pituitary.

2. The neurotransmitter that is considered to be the most important inhibitory neurotransmitter in the upper brain stem where sleep is regulated is:
   a. acetylcholine.
   b. dopamine.
   c. gamma aminobutyric acid.
   d. serotonin.

3. All of the abbreviations listed below represent electrophysiologic instruments used to observe and measure sleep EXCEPT:
   a. EEG.
   b. EGG.
   c. EMG.
   d. EOG.

4. The deep, restorative sleep of stage 2 and 3 that is described as truly restful sleep is:
   a. alpha sleep.
   b. beta sleep.
   c. gamma sleep.
   d. delta sleep.

5. The chemical that reportedly stimulates the production and release of interleukin-1 during sleep is:
   a. factor P.
   b. factor Q.
   c. factor R.
   d. factor S.

6. The function of interleukin-1 is to contribute to:
   a. dreaming and memory download.
   b. the body's defense against disease.
   c. digestion and assimilation of protein.
   d. maintaining respiration.

7. The type of insomnia that results from conditioned or learned insomnia which the individual associates with his bed, bedroom or sleep process is:
   a. hypercapnia insomnia.
   b. hypoxemia insomnia.
   c. psychosomatic insomnia.
   d. psychophysiologic insomnia.

8. Nocturnal myoclonus refers to:
   a. bed wetting.
   b. dreaming.
   c. muscle contractions.
   d. snoring.

9. The neurotransmitter that is a major stimulant for alertness and memory, and also helps to initiate and maintain REM sleep is:
   a. acetylcholine.
   b. dopamine.
   c. gamma aminobutyric acid.
   d. serotonin.

10. Which of the following activities is absent during NREM sleep?
   a. Brain waves
   b. Eye movement
   c. Muscle movement
   d. Respiration

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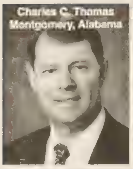
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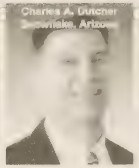
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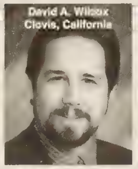
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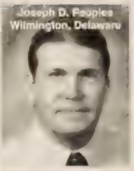
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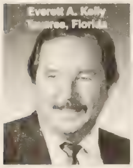
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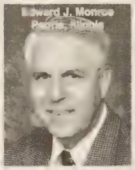
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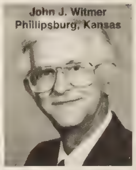
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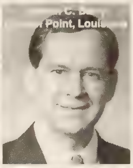
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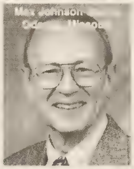
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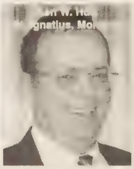
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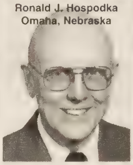
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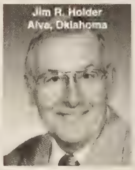
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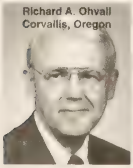
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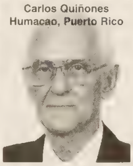
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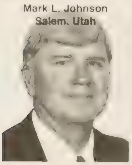
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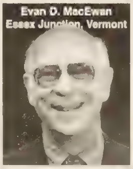
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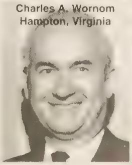
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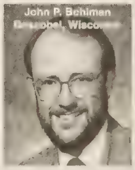
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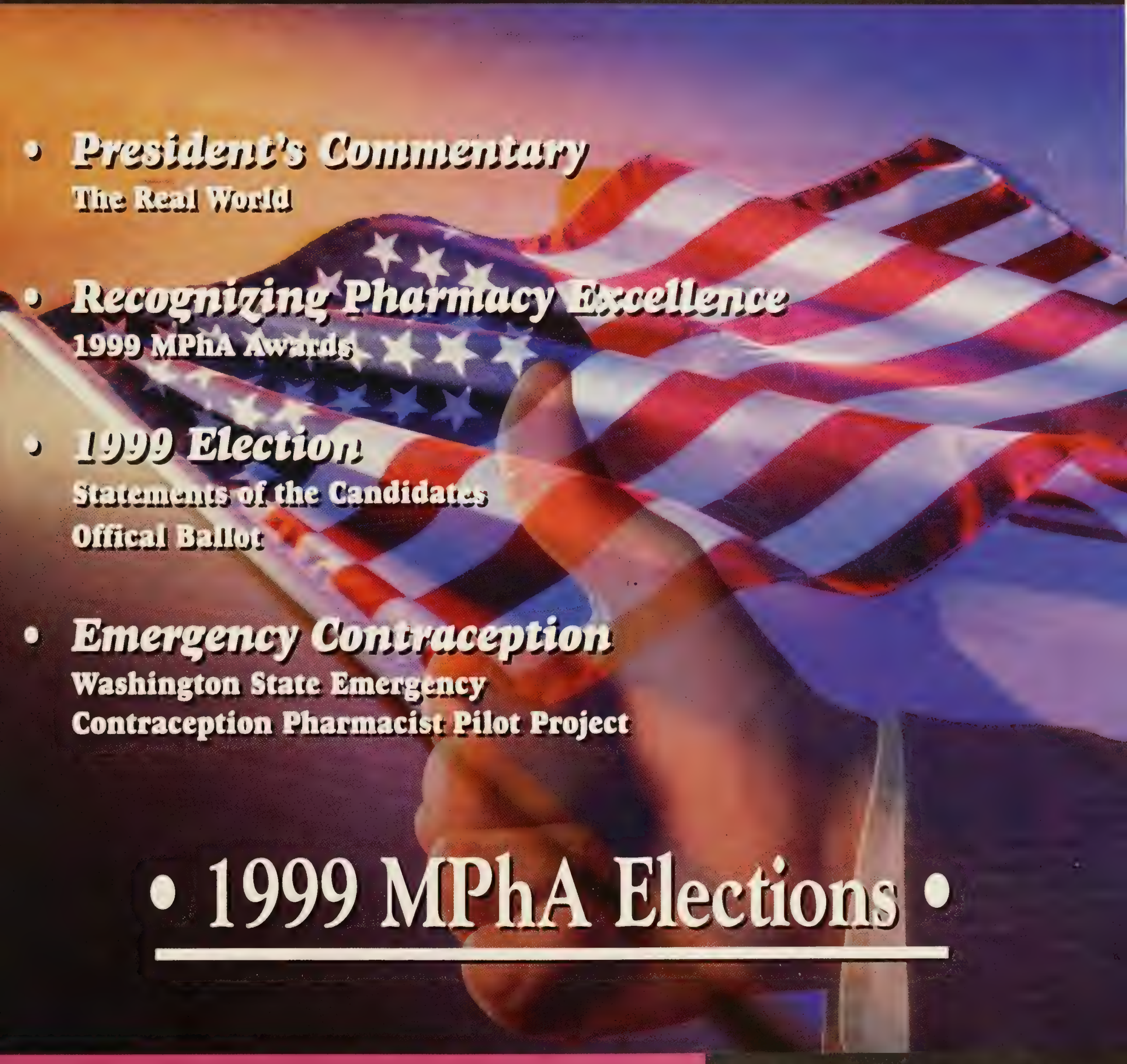

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President's Commentary

Gerard A. Herpel, P.D

Have you ever taken the time to think about who has influenced you the most in you practice of pharmacy? Did you have a mentor? Or, were there one or two really good preceptors who showed you the ropes and introduced you to the real world of pharmacy before you graduated from school?

Two Preceptors, John Balch of then Bedford Road Pharmacy in Cumberland and the late Renard Monti at the Drug Fair in Ocean City, come to mind when I think back to my formative years in the early eighties at the University of Maryland. They took the time to teach me the practical side of pharmacy. To this day I still use the knowledge and tips that these two great men passed on to me. I could never truly repay them. However, I do have the chance to bring students into my pharmacy and show them how I practice our profession and share with them that knowledge.

Many mentors influence the careers of young pharmacists as they forge their path into our profession. Most will tell you that it is a truly rewarding experience. Preceptors and students exchange ideas which both parties can learn from.

Have you thought to yourself … these kids coming out of school don't have a clue about the real world? Now is your opportunity to help them be prepared and to give something back to the profession. Being a preceptor does not take much time during the workday. Take a student under your wing. You never know—you might learn something about yourself.

If you are doing something special in your practice, allow students to see it first hand. What you might think is common and ordinary, might be a seed that sparks a student into changing their thinking about what pathway he or she will lead after graduation. In all practice settings we all have something to share with students who will be our future.

The University of Maryland is looking for more preceptors. *The Experiential Learning* is a series of structured learning and training activities during which students work under the supervision of experienced preceptors (pharmacy practitioners who have faculty appointments) and academic faculty in a variety of health care settings. Students obtain and apply knowledge and skills necessary for successful delivery of pharmaceutical care and develop competence, confidence, and maturity as responsible professionals.

Take the lead from Howard Schiff, MPhA's Executive Director, and become a preceptor. Call the University of Maryland or a school of your choice for more information.

Richard Rumrill, Director
Experiential Learning
University of Maryland
School of Pharmacy
410-706-4192

Director's Column

Howard R. Schiff, P.D.
Executive Director

Assisted Living Program Regulations

The new Assisted Living Program regulations went into effect on January 1. They replace any regulations that were in effect concerning domiciliary care homes. The emergence and growth of these homes has given seniors more choices for care and housing than ever before. Estimates are that nationwide there are 40,000 to 65,000 homes and increases in that number are expected.

The regulations run 20 pages long and are being implemented by a panel under the auspices of the State Licensing and Certification Administration. The panel meets every third Wednesday of the month in Room L-1 at 201 W. Preston Street in Baltimore from 4:00 to 6:00 p.m. and presumably will discuss problems and changes. Although no pharmacist was on the original panel, we have attended meetings and Mayer Handelman, who has worked with the panel, has recently been appointed.

There is consternation among pharmacists about the regulations because they give new residents' medication review and quarterly review responsibilities to nurses as well as pharmacists and physicians. Medication management training for non health care operators is mandated without specifics about who is qualified to give the training. We believe the health professional specifically educated and trained for these competencies is the pharmacist.

When questioned about these practices, the panel seemed satisfied that the regulations were workable. The problems most foreseeable were with smaller homes and not with upscale homes run by large corporations, although the line between assisted living homes and nursing homes in the larger homes can be very fine. Members of the panel who operated smaller homes mentioned several times that they had consulted the pharmacist who filled prescriptions for their residents and had resolved drug related problems because of the pharmacist's intervention. For those of us who have these patients, it is in our best interest to be aware of the patient's status. It is an excellent opportunity to perform pharmaceutical care and to volunteer for medication review. There is payment for this service in the regulations.

Whether the regulations are ideal in our minds or not, there is opportunity to perform a public service by pharmaceutical care and get paid for it. Knowledge of the regulatory changes and your patients' situation are the first steps. ***Be Aware and informed!***

Recognizing Pharmacy Excellence
The 1999 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 117th Annual MPhA Convention.

For consideration, all nominations must be received no later than ***Friday, April 16, 1999.***

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
  Awarded to a pharmacist who has graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. ***Who is Eligible:*** Any MPhA pharmacist member who graduated from pharmacy school in 1990 or after.

- **Maryland Pharmacists Association Honorary President**
  An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time.
  Who is Eligible: Any long standing contributor to the profession or the Association.

- **Seidman Distinguished Achievement Award**
  Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during ***either*** the past year or over a period of years. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

- **Wyeth-Ayerst Bowl of Hygeia Award**
  The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions.
  Who is Eligible: Any MPhA member pharmacist who has not already received the Bowl of Hygeia.

- **DuPont Innovative Practice Award**
  Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. This may include adding a new service, restructuring a pharmacy and its current services, or developing a completely new practice. ***Who is Eligible:*** Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association
Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be complete and returned to the Maryland Pharmacists Association no later than ***Friday, April 16, 1999***. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐***Pharmacist Mutual Distinguished Young Pharmacist Award***
Nominee ______________________________
Home Address ___________________________
City/State/Zip ___________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone _____________________________
Name of Nominator _______________________
Nominator's Phone _______________________

☐***Seidman Distinguished Achievement Award***
Nominee ______________________________
Home Address ___________________________
City/State/Zip ___________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone _____________________________
Name of Nominator _______________________
Nominator's Phone _______________________

☐***Dupont Innovative Practice Award***
Nominee ______________________________
Home Address ___________________________
City/State/Zip ___________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone _____________________________
Name of Nominator _______________________
Nominator's Phone _______________________

☐***Wyeth-Ayerst Bowl of Hygeia***
Nominee ______________________________
Home Address ___________________________
City/State/Zip ___________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone _____________________________
Name of Nominator _______________________
Nominator's Phone _______________________

☐***MPhA Honorary President***
Nominee ______________________________
Home Address ___________________________
City/State/Zip ___________________________
Current Place of Employment/Practice
____
Telephone ______________________________
Work Phone _____________________________
Name of Nominator _______________________
Nominator's Phone _______________________

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street, Baltimore, MD 21201-1572

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Awards Nominations
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for President-Elect

Murhl Flowers, P.D.
Safeway
4551 Forbes Blvd.
Lanham, MD 20706

West Virginia University School of Pharmacy
Graduation Year: 1965
Practice: Retail Community Pharmacy
Employer: Safeway

I have practiced pharmacy in Maryland for 34 years and have been involved in the Maryland Pharmacists Association for almost 20 years.

I have endeavored to be part of the solution with the issues facing pharmacy in Maryland by being involved whenever I have been needed. In the MPhA, I have been on the Board of Trustees for over thirteen years and have held numerous positions and chairmanships, including two terms as Speaker of the House of Delegates.

I have also worked with the Board of Pharmacy by participating on several task forces, including the task force in 1997 to rewrite the Pharmacy Practice Act. I am currently a member of the Pharmacy Technician Task Force as well as the Strategic Planning Committee concentrating on Collaborative Practice Legislation.

My pharmacy experience has been diverse: an employee pharmacists in both chain and independent setting; a hospital pharmacist and an independent Pharmacy owner. For the last 17 years, I have been the Pharmacy Director for the Eastern Division of Safeway.

At this point in my career, I look forward to the opportunity to further use my experience to continue strengthening the Maryland Pharmacists Association and furthering pharmacy in Maryland.

We face many challenges in Pharmacy, but working together we can address these issues collectively and can effect a strong degree of control over our own destiny. I humbly ask for your vote and support for the office of President of the Maryland Pharmacists Association.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for President-Elect

Joseph Marrocco, P.D.
3909 Eland Road
Phoenix, MD 21131

Duquesne University School of Pharmacy
Graduation Year: 1973
Practice: Retail Community Pharmacy
Employer: Giant

If elected to this position of President, I will devote my focus and energy to enable MPhA to "chart" the course, not merely to follow it, as changes continue to impact our pharmacy profession.

Pharmacists are demanding more from our organization, and my desire is to respond to you, our membership, in many ways. Resource information, such as our web site, (everybody's on the web, including us) should furnish you on up to date issues. Our membership should be able to reap the benefits of pharmacy industry consumer advertising for Rx medications and products, and be compensated too, for this and clinical trail growth on marketed drugs. Geriatric pharmacy is good news for the industry and our profession, but we must be prudent in our dealings with third parties to be sure that this growing segment of our patient base does not break the "bank."

I have been honored to serve you and MPhA for prior terms, presently as Vice-President for a second consecutive term, and prior as Speaker and Vice Speaker of the House of Delegates. These positions enabled MPhA to "team" on a number of important issues that reflect us all. I present to you my near perfect meeting attendance, work with the yearly terms of six diligent, dedicated presidents of your fine state association, whom like I, volunteer their time to keep our Maryland association at the forefront of pharmacy matters where/whenever applicable.

Presently, I also serve on the Building and Property Committee, a responsibility I have accepted for the past several years. The focus of my energy in this committee is immediate and urgent, as we are in the midst of finalized negotiations with our legal counsel, committee members, and the UMB campus area with the University of Maryland Medical System and School of Pharmacy, that will best serve our MPhA members for the present and for the many years to come. I also serve on our MPhA Convention Committee, for both the Summer and Mid-Year meetings, and hope to see many of you participating in "live" continuing education.

In final analysis, I pledge to you, my fellow pharmacists of all spheres of practice, an open door policy that is reflective and responsive to your concerns in your daily practice setting. I would welcome routinely your feedback and ideas of where our association should be pointing, and the course it should be "charting."

As your elected leader, I feel this mission is paramount and vital to us all. Thank you for your consideration and support. I would be honored to serve you and our most trusted profession of pharmacy.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for Vice President

Paul R. Holly, P.D.
9012 Scotts Haven Drive
Baltimore, MD 21234

West Virginia University School of Pharmacy
Graduation Year: 1970
Practice: Independent Community Pharmacy
Employer: Tuxedo Pharmacy

It would be an honor and a privilege to represent our profession as Vice President of MPhA. If elected, I will devote my time and energy to assist in providing guidance and direction to enable MPhA and its members to meet the many challenges of the next millennium.

Currently, I serve as a community pharmacist/manager in a professional medical building. Throughout my career, I have held positions in hospital pharmacy, government practice, and as a pharmacy store owner. In the capacity of retail pharmacist, I recognize and share your concerns of third parties, managed care, and pharmaceutical manufacturers. I believe we must continue to *strive* to have pharmacists compensated for cognitive services that we provide on a daily basis. We must continue to demonstrate that these daily services are paramount for positive patient outcomes.

My experience in working with the Board of Trustees has been extensive. I have held positions on the Membership and By-law committee. Currently, I serve as the Chairman of the Fund Raising Committee. The focus of my energy on this committee is immediate, as we must fund our expansion into a new building that will house our membership as well as allied pharmacy associations.

As a preceptor for students at the University of Maryland School of Pharmacy, I am committed to give something back to the profession and to offer incoming pharmacists the opportunity to experience, first hand, the practice of Pharmacy in a retail setting. By serving as the President of the local chapter of the Alpha Zeta Omega, a national pharmacy fraternity, I understand the need to provide continuing education to practicing pharmacists in order to keep them updated in the field.

With the rapid changes in health care, a strong association is critical to the preservation of *our* profession. *Our* strength lies in unity. If I am elected, I would welcome your feedback and ideas of where *our* association should be heading. My experience, and commitment, will enable me to contribute to the strength of *our* profession and *our* association. I ask for, and will appreciate, your support.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for Vice President

Mark Sanford, P.D.
401 W. Redwood St., Apt. 203
Baltimore, MD 21201

University of Maryland School of Pharmacy
Graduation Year: 1990
Practice: Hospital Pharmacy
Employer: University of Maryland Medical System

I served as MPhA Vice Speaker of the House of Delegates for 1994-95, Speaker of the House of Delegates from 1995-96, and Board of Trustees member from 1994 to 1999. I have been an active member of MPhA since 1987 and have served as a member and/or chairman of numerous committees. In addition, I have represented MPhA on the Continuing Education Coordinating Council (CECC), the Maryland Board of Pharmacy Task Force on Technician Credentialing, the Voice of Pharmacy Training program in Palm Springs, and the Maryland Pharmacy Leadership Conference.

I am also a past president of the University of Maryland School of Pharmacy Alumni Association and an active member of MSHP and ASHP. I received the Marion Merrell Dow Distinguished Young Pharmacists Award which recognizes leadership in the profession of pharmacy.

If elected to the office of Vice President, I will do my best to uphold the interests of all Pharmacists in the State of Maryland and strive to shape the future of our profession in a rapidly changing healthcare environment. I will work with the other officers, board of trustees, and MPhA members to achieve our common goals and help to advance the practice of pharmacy into the new Millennium.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for Treasurer

Lance Berkowitz, P.D.
2 Trotters Court #T-2
Baltimore, MD 21208

Medical College of Virginia
Graduation Year: 1965
Practice: Consultant
Employer: Practice Management Associates, Inc.

I am president of Practice Management Associates, Inc., a consulting firm specializing in managed health care. As a pharmacist, journalist and community activist, I have appeared on local and national radio and television commenting on health and education and I am also a noted local and regional newspaper columnist. I served during the Governor William Donald Schaefer administration as a member of the Maryland Board for Community Colleges where I helped govern a program with a $100 million budget and 78,000 students. I am past chairman of the board of the Harford Belair Mental Health Association, and I am past president of the Baltimore Metropolitan Pharmacists Association. I served at the invitation of Baltimore Cardinal William Keeler and Maryland Governor Schaefer on the executive committee of the Archdiocese of Baltimore's Tricentennial Benefit Concert, raising over $100,000 for Maryland's needy and I served as fund raising chairman of St. Dominick's School in Hamilton where I completed a $200,000 fund raising commitment. I was also one of the founders of the Harvest for Health, a nationwide program to collect and distribute thousands of pounds of health care products for the needy. In October 1995, I was selected as the 1995 recipient of the U.S. Pharmacist/Searle Service to the Community Award, the national award given to an individual pharmacist who has distinguished him or herself in the service of their community and their fellow citizens.

I will strive if re-elected treasurer, to continue to provide the association with a prudent approach to fiscal responsibility, and I will exhaust all possibilities in helping to raise additional funds to improve the Kelly Building or to support the "new" home of MPhA.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #1

Rhea del Rosario, R.Ph.
310 S. Riverside Drive
Crownsville, MD 21032

University of Maryland School of Pharmacy
Graduation Year: 1995
Practice: Retail Community Pharmacy
Employer: CVS Pharmacy

If elected to this position, I will devote my time and energy to provide guidance as the MPhA meets challenges to the 21st century. These challenges include pharmaceutical care, managed care, and collaborative practice, just to name a few. We must aggressively demonstrate that the cognitive services we employ daily are paramount for positive outcomes for all parties involved.

Presently, I serve as Speaker of the MPhA House. In addition, I served as Trustee for two previous terms, one of which I was a student as ASP President. This early involvement was an awakening to the significance of the MPhA to pharmacists and pharmacy students.

With the rapid changes in health care, a strong association is critical to the protection and preservation of our profession. It would be of great privilege and honor to continue to serve you as we move forward into the 21st century. Thank you for your consideration and support.

Charles A. Sandler, P.D.
400 S. Hammonds Ferry Road
Linthicum, MD 21090

University of Maryland School of Pharmacy
Graduation Year: 1962
Practice: Independent Community Pharmacy
Employer: Linthicum Pharmacy

I am past president of the School of Pharmacy Alumni Association and have served on its executive board since 1970. I am a member and past president of the AZO fraternity and have served on its executive board. I was a member of the executive board of BMPA until its merger with MPhA. I am now enrolled in the Pharm.D program at the University of Maryland.

While pharmacy is a profession, and we are concerned about delivering pharmaceutical care to our patients, we must also be concerned with the business side of pharmacy. Until we get paid for our knowledge in delivering services, we must be reimbursed at a reasonable fee for dispensing.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidates for Trustee Seat #2

Valarie Coons, R.Ph.
CVS Regional Business Office
11729 Beltsville Drive
Beltsville, MD 20705

Ohio Northern University School of Pharmacy
Graduation Year: 1991
Practice: Retail Community Pharmacy
Employer: CVS Pharmacy

I am the daughter of an independent store owner and have been in and around the community retail business for over 20 years. I also have experience in nursing home pharmacy as well as small and large chain pharmacy.

I currently hold the position of Regional Healthcare Manager and am fortunate to be part of many grass roots efforts aimed at improving our day to day practice of pharmacy, including the Technician Task Force for the Board of Pharmacy, the University of Maryland Educational Advisory Committee, and the MPhA Goals and Objectives Committee. I am also involved with MACDS and other groups who have positively impacted changes to recent Medicaid policy and who are actively working toward a pharmacy collaborative practices agreement.

There are many challenges facing us in the year ahead. With increased managed care and decreased reimbursements, we will have to work together within our association to preserve and protect our professional rights. I am committed to working on these pivotal issues that will shape our futures and the future of our practice. I ask for your support and thank you for your consideration.

Kevin McCarthy, R.Ph.
6210 Bryantown Drive
Bryantown, MD 20617

University of Maryland School of Pharmacy
Graduation Year: 1980
Practice: Retail Community Pharmacy
Employer: Safeway

Most recently, I have impacted our profession by serving on the Maryland Medicaid Task Force, and was instrumental in crafting recommendations that would favorably affect retail pharmacy. In addition, I have also served as an advocate of the profession in opposition to recent medicaid changes by the State that cause an undue burden on community pharmacy. I need your vote to increase our mandate to battle unreasonable and unworkable changes forced upon us by third party payors. I will be more effective in these efforts with your support.

Statements of the Candidates

1999 Maryland Pharmacists Association Elections

Candidate for Trustee Seat #3

Fred Abramson, P.D.
9 Rush Vine Court
Owings Mills, MD 21117

University of Maryland School of Pharmacy
Graduation Year: 1956
Practice: Faculty
Employer: University of Maryland School of Pharmacy

I owned my own community pharmacy from 1959 to 1982. Since that time I have been teaching at the University of Maryland School of Pharmacy. I enjoy teaching young people and giving them a perspective on the "real world." The students today are intelligent and enthusiastic and I try to teach them what to expect when they go into the job market.

I have frequently attended Board of Trustees meetings both as Honorary President and as a representative of the school. The MPhA is a dynamic, growing organization and I would like to be part of it. I believe that with my experience and outlook I can give something to the organization as a trustee. I thank you for your support.

Glenn Lichtman, P.D.
3408 Fielding Road
Baltimore, MD 21208

Howard University
Graduation Year: 1980
Practice: Independent/Other
Employer: PharmaSTAT

Due to my unique position as owner and director of PharmaSTAT, I encounter situations that occur in *all* pharmacy practice settings. For too many years our association has been perceived as just the retail pharmacists association. If our organization is to thrive in the new millennium, our goal must be to truly become the umbrella organization for *all* Maryland pharmacists. A trustee for the Maryland Pharmacists Association must have experience in all pharmacy practice settings. If elected, I will use my PharmaSTAT experience to help the association become an organization representing all licensed pharmacists in Maryland.

1999 Maryland Leadership Elections
Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

President-Elect

☐ Joseph Marrocco, P.D.

☐ Murhl Flowers, P.D.

Vice-President

☐ Mark Sanford, P.D.

☐ Paul Holly, P.D.

Treasurer

☐ Lance Berkowitz, P.D.

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

☐ Rhea del Rosario, R.Ph.

☐ Charles Sandler, P.D.

Trustee Seat # 2

☐ Valarie Coons, R.Ph.

☐ Kevin McCarthy, R.Ph.

Trustee Seat # 3

☐ Glen Litchman, P.D.

☐ Fred Abramson, P.D.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, *postmarked by Friday, April 30, 1999*. For questions, please call MPhA at 800-833-7587.

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1999 Maryland Leadership Elections
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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Y2K: Your System Vendor May be Ready...Are you?

By Chuck Reed

While the general public has just recently become aware of Year 2000 and its implications for software failure, it is not news to the companies that build software for a living. In the pharmacy management system industry where I have spent many years, it has been a topic of discussion since the early 1990's at industry gatherings.

In my opinion, most pharmacy system vendors have done a creditable job of making the necessary changes to their software and most claim to have completed their Year 2000 work.

However, just because your vendor is ready, doesn't mean you are. There are many potential pitfalls in the course of getting software from the lab to the pharmacy. Software distribution is always a big issue and now it is further complicated by non-compliant hardware and operating system issues.

The Root of the Problem

The problem arises from a long standing computer programming practice of using only two digits to represent a year. For example, 980518 is read as May 18, 1998, with the '19' assumed. It is the assumption of the 19 that is at the root of the problem. For most software programs ever written, unless a programmer modifies the software code in advance, when the software programs see '00' as the year they will incorrectly interpret it as the year 1900.

The crux of the problem is in how comparisons are affected. For example, your software will compare the date of a prescription being refilled on January 15, 2000, with the previous fill on December 12, 1999, to guard against early refills or warn of late refills. To determine the number of days since the last refill the software will compare 19991212 against 20000115 to determine 34 days. If however, the software were not modified, the January 15 date would be represented in the comparison as 19000115. The results would be unpredictable. In many cases, the programs would blow up and stop functioning. In some cases, programs may continue and give the illusion that no error has occurred. Many people feel that this result is worse than the first, especially where patient care is involved.

It's not just a software problem

Because hardware has embedded software in some of its chips, computer equipment is also at risk. My rule of thumb is that equipment purchased before 1997 and in some cases equipment purchased as late as 1997 is suspect. Most of the newer models that are not Y2K compliant have BIOS upgrades available to make them Y2K compliant. BIOS is software that resides in the chips of the hardware to boot it up. But, not all equipment can be repaired this way.

The software known as the operating system can also be a problem. Many older versions of DOS and UNIX, both of which you will still find in some pharmacies today, are not Y2K compliant.

Pharmacists are too trusting

In my experience, pharmacists have a very trusting nature. But, I think this is the time to not be so trusting, to express a little doubt and ask a lot of questions. For example, I am familiar with a vendor with over 1,000 pharmacies using its software that has gotten less than 50 written requests about Year 2000 readiness. Most of those were larger institutions with dedicated Year 2000 project teams. It's a little frightening —are the other 950 pharmacies even aware of the problem? Pharmacists should take a more assertive approach. There is too much at risk.

My checklist for pharmacists

Whether you are the director of pharmacy in a large hospital, owner of an independent community pharmacy, or an employee pharmacist, I recommend you take the initiative to see that your pharmacy is prepared.

Fixing the problem is not difficult, but it can be time consuming. That's why you don't want to wait too long. System vendors are going to be inundated with procrastinators next year and may not be able to provide the level of service you would like. You don't want to make decisions in a panic. So, here are my recommended steps that should be started as soon as possible.

1. Determine if your software vendor has completed their Year 2000 modifications. This must include field testing. If your vendor hasn't at least finished the programming, internal testing, and has it running at some sites, I would be worried. You may want to seriously consider switching to another system. At the very least, you should have some serious discussions with them. They are dangerously behind.

2. Identify computer equipment that is not Y2K compliant. If you bought your equipment from your pharmacy system vendor, they may be able to provide guidance. You can probably count on having to replace some equipment. And don't forget about old workstations that are important to the operation of your pharmacy. If you have equipment that needs BIOS upgrades your vendor may have the software patches available on diskette. If you bought the equipment on your own, check the manufacturer's Web site for guidance.

3. Can the new software be loaded on your equipment? It is possible that even if your computer is Y2K ready, it won't be able to handle the software release. It may be because the release is only available on CD-ROM and your system does not have a CD-ROM drive. Or, perhaps new functions are included in the release and they require more disk space or memory than your system has available. If there is any doubt at all, I recommend buying new equipment. It can be cheaper and less trouble than adding onto an old system, especially when you take into account warranty periods that can save money on maintenance costs.

4. Load the software. I don't know how often I have heard pharmacists complain that their system was not ready for some new industry change only to find out that the software release that contained the needed functionality had been sitting at the pharmacy for months. Don't delay. If you are going to have problems loading it, you want to know as soon as possible.

5. Run your own simple tests. When you've completed the first four steps, I highly recommend running your own simple tests. I just believe there are too many site-specific issues to rely fully on testing by the vendor. On some weekend or evening, set the computer's clock forward to December 31, 1999 and fill a few prescriptions. Then, set the computer forward to mid January 2000 and refill those prescriptions, maybe add a new patient and fill a new prescription. Think of possible failure points and be alert to actual behavior. The system won't necessarily blow up with an error—it may be subtle.

6. Are other areas at risk? Think about other areas of your business at risk. Do you have an accounting system? Is it Y2K ready? How about your cash registers? Fax machine? Phone system? All are potential failure points.

7. Contingency planning. What will you do if you do have problems? Can you bring in extra staff? Even if you don't have problems your doctors or others might—the extra staff might be helpful. On the more alarming side—what will you do if your primary third party is down? How will you handle those customers? What if it goes on for a while—how will you handle the squeeze on cash? Be alert to things you hear in your area and imagine different scenarios. Then do what you can to mitigate them.

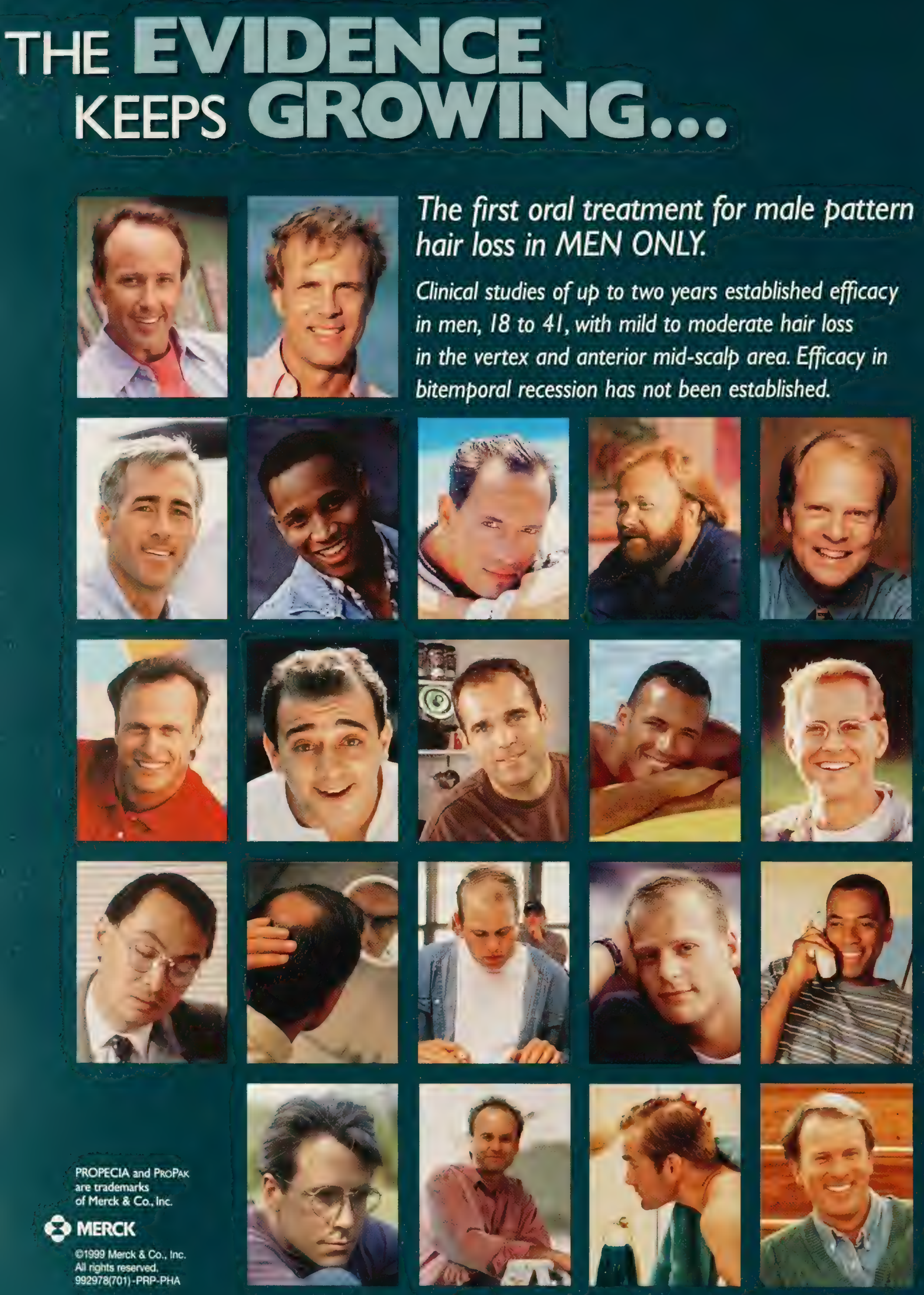
8. Turn the computer off on New Year's Eve. More and more pundits are suggesting this for every computer from mainframes to PC's. There are whole classes of possible failure points associated solely with the ‘click over’. Why risk it? Even if you are open 24 hours, turn the system off before midnight and boot it up again afterwards. I think I might even save some of the prescriptions from December 31 and come in New Year's Day to enter them. I think I would enjoy New Year's Day a lot more knowing that my system is up and running in the Year 2000!

Chuck Reed, a veteran of the pharmacy management system industry, is president and founder of Chromis Inc., which provides software and consulting services to healthcare system developers. He is also the immediate past-president of the American Society for Automation in Pharmacy. He can be reached at chuck@chromisinc.com.

This article is made available to you through the courtesy of the American Pharmaceutical Association.

THE EVIDENCE KEEPS GROWING...

Propecia™
(finasteride)
Helping make hair loss history™



THE EVIDENCE
KEEPS GROWING...

The first oral treatment for male pattern hair loss in MEN ONLY.

Clinical studies of up to two years established efficacy in men, 18 to 41, with mild to moderate hair loss in the vertex and anterior mid-scalp area. Efficacy in bitemporal recession has not been established.

PROPECIA and PROPAK are trademarks of Merck & Co., Inc.

MERCK

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992978(701)-PRP-PHA

STUDY AFTER STUDY

Maintains hair count

83% of men maintained or increased hair count at 24 months in vertex studies (v. 28% placebo). Early benefits of slowing hair loss can be seen at Month 3 based on patient self-assessment. A new 12-month study showed that PROPECIA increases hair count by increasing the number of hairs that are actively growing ($p<0.001$ v. placebo).[1]

PATIENT AFTER PATIENT

Regrows natural, visible hair

66% of men had visible hair regrowth in vertex studies (v. 7% placebo) based on global photographic assessment. In addition, investigators rated 80% of patients as improved (v. 47% placebo).

Excellent safety profile

Each drug-related adverse event occurred in <2% of men.

Adverse events at 12 months	PROPECIA 1 mg (N=945)	Placebo (N=934)
Decreased libido	1.8%	1.3%
Erectile dysfunction	1.3%	0.7%
Ejaculation disorders	1.2%	0.7%
(Primarily decreased ejaculate volume)		

Patients completed a self-administered questionnaire to detect more subtle changes in sexual function; results were consistent with the above table. No significant difference was seen in overall satisfaction with sex life.

Convenient oral, once-daily dosing

Recommend ProPak™— a convenient 3-month supply of PROPECIA that includes a cash back offer for patients.

For use in MEN ONLY

Women who are or may potentially be pregnant must not use PROPECIA nor should they handle crushed or broken PROPECIA tablets because doing so may cause abnormalities of the external genitalia of a male fetus.

If PROPECIA has not worked within 12 months, further treatment is unlikely to be of benefit.

Before dispensing PROPECIA, please read the brief summary of Prescribing Information on the following page.

Propecia™
(finasteride)

Helping make hair loss history™

THE **EVIDENCE** KEEPS **GROWING...**

Recommend ProPak™

Propecia™
(finasteride)

Visit our website at www.propecia.com

Helping make hair loss history™

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1. Data available on request from Professional Services, WP1-27, Merck & Co., Inc., West Point, PA 19486. Please specify information package DA-PRP3.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. (See also WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; and PRECAUTIONS, *Information for Patients* and *Pregnancy*.) In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

Hypersensitivity to any component of this medication.

WARNINGS

PROPECIA is not indicated for use in pediatric patients (See PRECAUTIONS, *Pediatric Use*) or women. (See also PRECAUTIONS, *Information for Patients* and *Pregnancy*.)

EXPOSURE OF WOMEN–RISK TO MALE FETUS

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; PRECAUTIONS, *Information for Patients* and *Pregnancy*.)

PRECAUTIONS

General

Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Information for Patients

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; and PRECAUTIONS, *Pregnancy*.) See also Patient Package Insert.

Drug/Laboratory Test Interactions

In clinical studies with PROPECIA in men 18-41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at Month 12. When finasteride is used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Until further information is gathered in men >41 years of age without BPH, consideration should be given to doubling the PSA level in men undergoing this test while taking PROPECIA.

Drug Interactions

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no interactions were found.

Other concomitant therapy: Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, α-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

Impairment of Fertility

In sexually mature male rabbits treated with finasteride at 80 mg/kg/day (4,344 times the estimated human exposure) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 80 mg/kg/day of finasteride (488 times the estimated human exposure), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats and is not relevant in man.

Pregnancy

Teratogenic Effects: Pregnancy Category X
See CONTRAINDICATIONS.

PROPECIA is not indicated for use in women.

Administration of finasteride to pregnant rats at doses ranging from 100 µg/kg/day to 100 mg/kg/day (5-5,000 times the recommended human dose of 1 mg/day) resulted in dose-dependent development of hypospadias in 3.6 to 100% of male offspring. Pregnant rats produced male offspring with decreased prostatic and seminal vesicular weights, delayed preputial separation, and transient nipple development when given finasteride at ≥30 µg/kg/day (≥1.5 times the recommended human dose of 1 mg/day) and decreased anogenital distance when given finasteride at ≥3 µg/kg/day (one-fifth the recommended human dose of 1 mg/day). The critical period during which these effects can be induced in male rats has been defined to be days 16-17 of gestation. The changes described above are expected pharmacological effects of drugs belonging to the class of Type II 5α-reductase inhibitors and are similar to those reported in male infants with a genetic deficiency of Type II 5α-reductase. No abnormalities were observed in female offspring exposed to any dose of finasteride *in utero*.

No developmental abnormalities have been observed in first filial generation (F_1) male or female offspring resulting from mating finasteride-treated male rats (80 mg/kg/day; 488 times the human exposure) with untreated females. Administration of finasteride at 3 mg/kg/day (150 times the recommended human dose of 1 mg/day) during the late gestation and lactation period resulted in slightly decreased fertility in F_1 male offspring. No effects were seen in female offspring. No evidence of malformations has been observed in rabbit fetuses exposed to finasteride *in utero* from days 6-18 of gestation at doses up to 100 mg/kg/day (5,000 times the recommended human dose of 1 mg/day). However, effects on male genitalia would not be expected since the rabbits were not exposed during the critical period of genital system development.

The *in utero* effects of finasteride exposure during the period of embryonic and fetal development were evaluated in the rhesus monkey (gestation days 20-100), a species more predictive of human development than rats or rabbits. Intravenous administration of finasteride to pregnant monkeys at doses as high as 800 ng/day (at least 750 times the highest estimated exposure of pregnant women to finasteride from semen of men taking 1 mg/day) resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a very high dose of finasteride (2 mg/kg/day; 100 times the recommended human dose of 1 mg/day or approximately 12 million times the highest estimated exposure to finasteride from semen of men taking 1 mg/day) to pregnant monkeys resulted in external genital abnormalities in male fetuses. No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

Nursing Mothers

PROPECIA is not indicated for use in women.

It is not known whether finasteride is excreted in human milk.

Pediatric Use

PROPECIA is not indicated for use in pediatric patients.

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Clinical Studies for PROPECIA (finasteride 1 mg) in the Treatment of Male Pattern Hair Loss

In controlled clinical trials for PROPECIA of 12-month duration, 1.4% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably, or definitely drug-related (1.6% for placebo); 1.2% of patients on PROPECIA and 0.9% of patients on placebo discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably, or definitely drug-related in ≥1% of patients treated for 12 months with PROPECIA or placebo, respectively: decreased libido (1.8%, 1.3%), erectile dysfunction (1.3%, 0.7%) and ejaculation disorder (1.2%, 0.7%; primarily decreased volume of ejaculate:[0.8%, 0.4%]). Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in all men who discontinued therapy with PROPECIA due to these side effects and in 58% of those who continued therapy.

In a study of finasteride 1 mg daily, in healthy men, a median decrease in ejaculate volume of 0.3 mL (–11%) compared with 0.2 mL (–8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median decreases of approximately 0.5 mL (–25%) compared to placebo in ejaculate volume but this was reversible after discontinuation of treatment.

In the clinical studies with PROPECIA, the incidences for breast tenderness and enlargement, and for hypersensitivity reactions in finasteride-treated patients were not different from those in patients treated with placebo.

Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR (finasteride 5 mg) in the Treatment of Benign Prostatic Hyperplasia

In controlled clinical trials for PROSCAR of 12-month duration, 1.3% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably, or definitely drug-related (0.9% for placebo); only one patient on PROSCAR (0.2%) and one patient on placebo (0.2%) discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably or definitely drug-related in ≥1% of patients treated for 12 months with PROSCAR or placebo, respectively: erectile dysfunction (3.7%, 1.1%), decreased libido (3.3%, 1.6%) and decreased volume of ejaculate (2.8%, 0.9%). The adverse experience profiles for patients treated with finasteride 1 mg/day for 12 months and those maintained on PROSCAR for 24 to 48 months were similar to that observed in the 12-month controlled studies with PROSCAR. Sexual adverse experiences resolved with continued treatment in over 60% of patients who reported them.

Adverse Effects Reported in Post-Marketing Experience for PROSCAR (finasteride 5 mg)

Breast tenderness and enlargement, as well as hypersensitivity reactions, including lip swelling and skin rash have been reported.

DOSAGE AND ADMINISTRATION

The recommended dosage is 1 mg once a day.

PROPECIA may be administered with or without meals.

In general, daily use for three months or more is necessary before benefit is observed. Continued use is recommended to sustain benefit. Withdrawal of treatment leads to reversal of effect within 12 months.

For more detailed information, please read the complete Prescribing Information.

PROSCAR is a registered trademark of Merck & Co., Inc

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Y2K Web Site Reference

The following table lists several web sites you may want to visit which may help you determine your readiness and those that offer related services and information.

Information	Address...http://www.
Healthcare Related issues	***Rx2000.org***
Commercial off the Shelf Software (COTS) - compliance information	Y2K.policyworks.gov mitre.org/technology/y2k
Specific products and information regarding compliance..	
Acer America (800-637-7000)	acer.com
AST Computer (800-727-1278)	ast.com
Compaq Computer (800-OK-COMPAQ)	compaq.com
Dell computer Corporation (800-560-8324)	dell.com
Gateway2000 (800-846-2301)	gateway.com
Hewlett-Packard (800-752-0990)	hp.com
Hitachi PC (800-555-6820)	hitachipc.com
IBM (800-772-2227)	us.pc.ibm.com
Intel (800-538-3373)	intel.com
Micron Technology (800-349-6972)	micron.com
Microsoft	microsoft.com/year2000
NEC Commputer Systems (800-456-9327)	nec.com
Packard-Bell (800-733-4411)	packardbell.com
Sony Electronics (800-352-7669)	sel.sony.com
Texas Instruments (800-848-3927)	ti.com
Toshiba (800-999-4273)	toshiba.com
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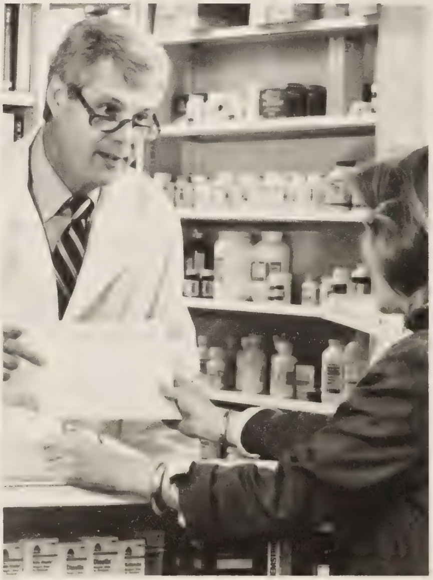

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Regulating the Pharmacist's Right of Conscience

By: David B. Brushwood

Within the past year, two influential pharmacy organizations (the American Pharmaceutical Association—APhA—and the American society of Health-System Pharmacists—ASHP) have formally considered the issue of conscientious objection by pharmacists. While few who have followed the issue closely would say that they are completely satisfied with the results achieved by these organizations, at least this difficult and potentially divisive issue is being openly discussed, and people who fundamentally disagree are learning to talk to each other. Few problems of major significance are resolved quickly, and the question of how to accommodate individual conscience in pharmacy is not likely to be an exception.

Yet, a solution must, and will, be found. The Joint Commission of Accreditation of Healthcare Organizations (JCAHO) requires that accredited institutions have a policy on conscientious objection (although it does not specify what the policy must be). Many employers of pharmacists in the community setting have developed their own policies that do not necessarily reflect careful consideration of pharmacist views and/or patient needs. Advocacy groups of similar-thinking pharmacists have proposed policies that reflect their own views, and have challenged the profession to adopt these policies for all pharmacists. Despite the attention that conscientious objection has received, however, no clear consensus has developed on the issue.

Timid pharmacy leaders may wish the issue would go away because it is emotional, intellectually challenging, and politically dangerous. But this is an issue that cannot be ignored. Morally troubling uses of medication, such as assisted dying, the morning-after pill, and abortifacient drugs, will become more prevalent in the future, not less. Heads must come out of the sand.

The pharmacist's appeal to individual conscience poses questions for the pharmacy profession that are different from those usually addressed when a pharmacist objects based on an appeal to professional duty. The appeal to individual conscience is personal and subjective. It is founded on beliefs about right and wrong, and it is motivated by personal sanction rather than by external control. The pharmacist who objects as a matter of conscience says, "I cannot do that because I could not live with myself if I were to do it."

The appeal to professional duty, by way of contrast, is altruistic and objective, it is founded on scientific evidence and clinical observation, and it is motivated by professional standards. The pharmacist who objects as a matter of duty says, "I cannot do that because it would be contrary to my professional responsibilities."

A pharmacy leader who says, "Of course pharmacists have a right to object to drug therapy as a matter of conscience if the therapy is potentially harmful to the patient or if it is illegal" has missed the point. The appeal to conscience is not about harming others; it is about harming one's self. The appeal to conscience and the appeal to the professional duty are as different as are asthma and chronic obstructive pulmonary disease. They may be similar, and they may seem the same, but they are profoundly different, and treating them as if they are the same will not work.

Care must be taken to avoid wasting time on the non-issue presented by the pointless question of whether patient rights trump pharmacist rights or vice-versa. There are no trump cards. This is a false choice. Just as we can choose to have pharmacists responsible for managing both hypertension and diabetes, and we can require that new drugs be shown to be both safe and effective, we can also respect both the patient's right to receive medication and the pharmacist's right of conscience. This will not be easy, but neither are disease state management or clinical drug trials. With sufficient effort and a spirit of cooperation rather than confrontation, the profession can develop systems through which all patients who need medication that are legal and appropriate get them, while pharmacists who object to dispensing medications they believe are morally wrong do not have to do so.

My contention has always been that the institution in pharmacy that should develop a system for conscientious objection is the board of pharmacy. The system, once it is developed, must effectively mediate between pharmacists and those who manage pharmacy practice sites.

The system must also comprehensively apply to all pharmacists and pharmacies, not selectively apply to some pharmacists and pharmacies. The board of pharmacy is the only pharmacy institution that has authority over both pharmacists and their practice sites and over all pharmacists and pharmacies.

Pharmacist groups, through their houses of delegates, may adopt conscientious objection policies, but these are meaningless in the day-to-day practice of the profession. Nothing happens when they are ignored. Pharmacy corporations may voluntarily establish policies that respect pharmacists' consciences, but voluntary policies can be changed without notice. The public deserves to know with certainty under what circumstances and through what procedures their prescriptions will be filled. Only the board of pharmacy can guarantee consistent application of a comprehensive rule, so that access to legal and appropriate medications is not unnecessarily impeded.

Understandably, boards of pharmacy have been reluctant to enter the controversial thicket of the conscientious objection debate. To say that board members are political is to restate the abundantly obvious. Politicians survive the longest by staying to the center, and conscientious objection is an issue that may appear to have no center.

The following are just some of the reasons I have heard for boards not wanting to become involved in this issue, along with corresponding counterpoints.

This has nothing to do with protecting the public health -
While it may be correct to say that respecting the pharmacist's right of conscience does not directly affect the public health, the reality is that refusal to provide medications does affect the public health. It may be that patients who have been refused medication can simply take their business elsewhere and be neither harmed nor inconvenienced, but that may not be the case. Decreased access to medications has the potential to affect public health, so it is a board of pharmacy issue.

You can't regulate morality -
Actually, we can, and do regulate morality. It is illegal to steal from each other and cheat each other because it is immoral to do so, but this begs the question. For a board of pharmacy to mandate a system that accommodates individual conscience of pharmacists and assures access to medication for patients would be a morally neutral action. This is not taking sides: it is simply requiring a system in which all sides are respected.

This is a local issue -
Pharmacy practice environments differ considerably, as do the social contexts within which they occur. It would be difficult to develop a single, one-size-fits-all policy on conscientious objection that would work in every practice site. But a board does not need to approach the problem from that perspective. To require a system that meets certain fundamental criteria would suffice. A board rule on conscientious objection need not be so prescriptive that it ties the hands of everyone and does more harm than good.

This is too difficult for me -
I think this is at the heart of most resistance to address the issue of conscience. Yet, boards of pharmacy have addressed conceptually difficult issues before, and they can do it again. There is a temptation to oversimplify the issue by dividing pharmacists into the categories of "moral" and "immoral," or "liberal" and conservative," or "religious" and "non-religious." Such labels really do not help at all.

A few hours of studying the issue can enable members of boards of pharmacy to understand the needs of all parties to the issue, and a system of accommodation can be developed based on this understanding.

State boards of pharmacy need to get into the game that is being played by other representatives of organized pharmacy because pharmacy practice standards on conscientious objection are being developed without significant board input. There is nothing wrong with having the profession develop standards, but boards should provide input because only boards can enforce standards.

The worst case scenario is to have an unenforceable standard, and to then be held accountable for having failed to do the impossible. This is worse than nothing. Because of the unique position they hold within pharmacy, with authority over all pharmacists and all pharmacies, boards of pharmacy can bring a unique and necessary perspective to the standard development process. The sideline may be safe and painless, but it is the wrong place to be as this game is being played.

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Counseling Guide for Pharmacists **Compliments of Pharm/alert®**

A healthy prostate gland is essential to male fertility. Secretion of this gland—which is located at the neck of the badder and surrounds the urethra—help ensure sperm motility and prevent infections in the urethra.

Disorders of the prostate gland include prostatic enlargement or benign prostatic hypertrophy (BPH), prostatitis, and prostate cancer. Of these, BPH occurs most frequently, with prevalence incresing as a man ages: about 5-10% of men will have prostate enlargement at age 30, while about 90% of men over 85 have it.

Symptoms of BPH include increased urinary frequency, nocturia, an increased sense of urgency to urinate, lower volume and weaker urinary flow, and difficulty emptying the bladder completely.

A yearly digital rectal examination (DRE) to assess prostate status would be prudent for men over 40. However, the prostate may not be sufficiently enlarged to be recognized by physical examination alone and ultrasound may be required for a conclusive diagnosis of BPH. When detectable via physical examination, a prostate gland enlarged due to BPH will generally feel softer and may be two or three times larger than normal (the normal prostate is about the size of a walnut). In the presence of BPH, the prostate is not tender, which differentiates it from prostatitis. And when prostate cancer is present, the prostate usually feels much harder.

Because symptoms of BPH and prostate cancer can be similar, a simple blood test called a prostate-specifid antigen (PSA) test should be performed to differentiate the two. Normal PSA values are <4 ng/mL; a level >10 is highly indicative of prostate cancer. The American Urology Association suggests that both PSA and DRE be offered annually to men over 50 to screen for proatate cancer.

Saw palmetto (Serenoa repens) is an interesting herb that has demonstrated efficacy in reducing BPH symptoms. In a study of 305 men, 80-90% experienced symptomatic relief within 30 days of treatment with 160 mg b.i.d. saw palmetto (Current Therapeutic Research 55:776, 1994). Urinary flow increased, prostate size decreased and overall quality of life definitely improved.

Numerous other clinical studies, including double-blind trials comparing this herb with placebo or other active agents, have shown excellent efficacy for saw palmetto in BPH. About 90% of men with mild to moderate BPH report at least some improvement in symptoms during the first 4-6 weeks of treatement. All major BPH symptoms have been relieved, particularly nocturia. Sleep deprivation resulting from constant awakening to urinate has a deleterious effect on the psyche and overall quality of life, so relief of nocturia is particularly beneficial.

The best outcomes occur when saw palmetto extract, standardized to contain 85-95% fatty acids and sterol, is given at a dose of 160 mg b.i.d.

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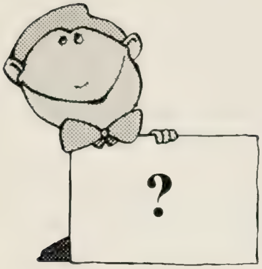


Did you know?

Shaving a beard was popular in Europe in the 19th century before it became the fashion here. King Gillette started the safety razor business in 1895 and had mild success. When World War I started and the brass saw the clean shaven French, the American army supplied razors and blades to the doughboys. Shaving became popular and it has remained so to this day.

Castile soap first appeared in Spanish literature in the eighth century and is made from olive oil and sodium hydroxide. It has been used for everything from the manufacture of pills (1900) to infant care and tooth powder (1926).

Why is sodium carbonate put into boiling water in which surgical instruments are to be disinfected? It prevents the instruments from rusting and also aids in the removal of any greasy matter which might prevent complete sterilization.

Why should prescriptions be written in Latin?

- It is a language understood throughout the world.
- It is a dead language, and, therefore, is not changing.
- Common names vary in different parts of the country, while Latin ones are distinctive.
- Technical Latin is not usually understood by the patient, and so there is not the danger of arousing prejudice.
- The tendency to self-medication is not increased. *From Whys' in Pharmacy-1927*

Ancient history
The symbol "℞" is actually a corruption of the ancient symbol for the Roman god Jupiter, whose blessing was invoked upon every prescription to ensure its purity.

State Board Questions/Answers, Circa 1926

What percentage of phenol is soluble in water?
    5% practically; 6⅔% at 25° C.
What will increase the solubility of phenol in water?
    The addition of glycerin.
What percentage is soluble in alcohol?
    Very soluble.
Name ingredients in the formula for solution of magnesium citrate.
    Magnesium carbonate, citric acid, syrup, purified talc, oil of lemon, potassium bicarbonate and distilled water.
What are the so-called "green and yellow molds," and how do they differ from black mold?
    In reality these are mildews belonging to the class of fungi known as Ascomycetes. The common green mold is *Penicillium glaucom*, and the yellow form, a species of Aspergillus. Both of these have segmented hyphae and produce chains of naked spores called conidia, while the black mold has unsegmented hyphae and its spores are enclosed within the spore case. *If they only knew!*

Information obtained from the E. F. Kelly Memorial Building Library

Interactions...

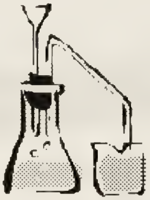
Building Solutions for Science

David A. Knapp, Ph.D.
University of Maryland School of Pharmacy

Pharmacy's strength as a health profession depends in large part upon its strong pharmaceutical science base. Medications work and patients know it! The key to new and better medications is improved understanding of mechanisms of action and the ability to discover new entities to combat disease.

Pharmaceutical education is founded on science. Science that, when coupled with clinical education, communication skills and professional experience, translates into successful and trusted pharmacists.

The Pharmaceutical Sciences Department, chaired by Dr. Russell DiGate, includes over 30 Ph.D. trained individuals in areas as diverse as chemistry, molecular and cell biology, whole-animal pharmacology, biopharmaceutics and pharmacokinetics. In addition to their contribution to the education of pharmacy students, the science faculty has built a Ph.D. program with more than 80 students and is pulling together a research program of national repute.



Last year, the group garnered external support for their research of more than $3 million from NIH and other federal agencies and the pharmaceutical industry. Two new science faculty members have been added within the last few months—Dr. Angela Wilks from the University of California at San Francisco and Dr. Andrew Coop from NIH. The department is searching for an additional five members.

With growth comes challenge. The School does not have sufficient space to accommodate the success of the science program. We have been unable to recruit three senior-level professors over the last three years because there is no space for their programs. Even our recent success in growing our research programs internally will be stymied without the ability to provide adequate physical facilities for successful scientists.
The solution is the Health Sciences Facility II—the science building. The proposed science building is to be shared by the Schools of Medicine and Pharmacy and provides a permanent home for dozens of basic science faculty members. The School of Pharmacy will occupy about 30% of the building, or close to 30,000 net square feet. This will provide the space necessary not only to relieve our current overcrowding, but also to permit growth in an era when biomedical research spending is expected to increase dramatically. The state's investment in this building will not only contribute to progress in pharmaceutical research but will provide economic benefits to the state from the fruits of scientific progress.

The proposal for the construction of the science building is before the Maryland General Assembly during its current term. MPhA members can help move this project along by writing their individual delegates and senators. The message is a simple one: Support building UMB's science building now! Your letter should include the following points:

- ✶ It is critical to build the Health Sciences Facility II now.
- ✶ The building will permit the Schools of Pharmacy and Medicine to build upon their strong records of biomedical research by providing adequate and well-equipped space.
- ✶ Approving the building now will allow the campus to take advantage of increased federal and industrial research spending in the biomedical sciences.

- The building is critical to eliminate overcrowding and permit growth in research.
- The building will stimulate economic development based upon public/private partnerships in scientific research.
- Strengthening the pharmaceutical sciences strengthens the professional education program for our pharmacy students.
- All people in Maryland will be positively impacted by the outstanding research this building will promote.

If you need to find the names of your senators and delegates or would like assistance in drafting a letter please contact David Marshall at the School of Pharmacy, 410-706-4415 or consult the General Assembly webpage @ http://mlis.state.md.us/. More information about the Health Sciences Facility II—the science building—is on the School of Pharmacy webpage at HYPERLINK http://www.pharmacy.ab.umd.edu

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Continuing Education for Pharmacists

Volume XVI, No. 9

Patient Counseling: New Drugs of 1998: Plavix, Avapro and Teveten

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Goals. The goals of this lesson are to identify and discuss new drugs approved by FDA in late 1997 and introduced to the marketplace during 1998.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for the drugs presented;
2. select from a list, the indication, mechanism of action, benefits and limitations of these drugs;
3. identify adverse reactions, major toxicities, and drug interactions associated with these products; and,
4. demonstrate an ability to counsel patients on these drugs.

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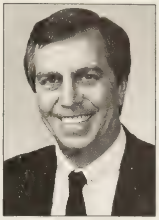

Wuest

Clopidogrel (Plavix)

Clopidogrel [Clo-pid-o-GREL/Plaa-VICKS] is a platelet aggregation inhibitor that directly inhibits adenosine diphosphate (ADP) from binding to its receptor sites on platelets. It is available in 75mg tablets.

The Disease. To review the clotting mechanism, when blood vessels are injured, the body's initial defense to prevent excessive blood loss stimulates platelet aggregation in the vicinity of the event, and releases chemicals involved in the clotting mechanism. This process allows platelets to clump together over the injury to form the "hemostatic plug." This covers the opening, prevents excessive blood loss, and initiates the formation of the permanent fibrin clot.

While this is necessary for hemostasis, the same events can occur excessively (and without a precipitating injury) in the arteries of patients with atherosclerosis and other clotting disorders leading to unwanted blood clot (thrombus) formation. When a thrombus breaks loose from its anchor at the point of formation on the blood vessel wall, it travels with the blood flow as an embolus into narrower passages (i.e., arteries to arterioles to capillaries) to the point where it is too large to move. There it lodges, and blocks the advance of blood and oxygen to tissues supplied by that blood vessel.

Since cells supplied with oxygen from the blood cannot live in its absence, they will soon die. In many areas of the body, there is sufficient collateral circulation to provide adequate blood flow into that area and there is little, if any, permanent tissue damage.

However, when a sufficient number of thrombi form and break loose (thromboembolism) to lodge in and prevent proper blood and oxygen supply to an end organ, the system is overwhelmed. The cells deprived of oxygen die (tissue necrosis) and the function they perform is lost.

The two organs that are affected most significantly are the heart and brain. Inadequate blood and oxygen supply (ischemia) to the heart can lead to sufficient tissue necrosis (myocardial infarction) to initiate arrhythmias. Because the heart's tissue is not able to conduct electrical impulses or contract properly, ventricular tachycardia and death can result.

In the brain, ischemia and tissue necrosis lead to a loss of function of the affected area. The result is a stroke (cerebrovascular accident), which if extensive can also cause death.

Another morbid result of thromboembolism is excessive blockage of blood vessels in the lungs (pulmonary embolism). This can lead to severe cardiac congestion and death. Peripheral vascular diseases are also aggravated by excessive platelet aggregation.

Therapy. Patients with a

Table 1
Commercially Available Platelet Aggregation Inhibitors

Generic Name	Trade Name	Dosage Forms	Usual Dose
Aspirin	various generics	81, 165, 325mg tablets	325mg once daily
Clopidogrel	Plavix	75mg tablets	75mg once daily
Dipyridamole	Persantine generics	25, 50, 75mg tablets	75-100mg q.i.d.
Ticlopidine	Ticlid	250mg tablets	250mg b.i.d. with food

tendency toward thromboembolism, especially those who have suffered from and survived a myocardial infarction, are treated prophylactically with platelet aggregation inhibitors (PAI). Currently, there are several different types of PAI. The three most commonly used are aspirin, dipyridamole and ticlopidine (Ticlid). Clopidogrel's action is similar to ticlopidine but totally different from aspirin and dipyridamole. Commercially available platelet aggregation inhibitors are listed in Table 1.

Aspirin inhibits platelet cyclooxygenase which prevents the formation of thromboxane A_2, one of the mediators of platelet aggregation. Reducing the formation of thromboxane A_2 reduces platelet aggregation, and lessens the chance of excessive clot formation.

Dipyridamole is a phosphodiesterase inhibitor with reported selectivity to the type of phosphodiesterase contained in platelets. Inhibiting this enzyme reduces the breakdown of cyclic adenosine monophosphate (cAMP) in the platelets, which also lessens platelet aggregation and excessive clot formation.

Plavix (and Ticlid), as stated earlier, inhibit adenosine diphosphate (ADP) from binding to its receptor sites on platelets. Fibrinogen, the precursor to fibrin, is an extremely important component of permanent clot formation. Fibrinogen is soluble in the blood and is always ready to be converted into fibrin when needed.

This conversion is initiated by the chemicals released from platelets when they aggregate and lyse. Fibrin is insoluble. When formed, fibrin precipitates and adheres to the hemostatic plug to eventually surround it. This becomes the permanent clot. Fibrinogen itself induces platelet aggregation by binding to a glycoprotein complex on the surface of the platelets.

The binding of fibrinogen to this complex is activated by ADP. Clopidogrel forms a selective, irreversible bond with this same complex for the life of the affected platelet. This, then, inhibits the ability of fibrinogen to induce platelet aggregation.

Plavix was given priority consideration for approval by the FDA because it is considered to have a better safety profile than ticlopidine since it does not induce adverse hematologic reactions. It also causes less gastrointestinal upset and hemorrhage than either ticlopidine or aspirin. It was approved on the basis of a single clinical trial, only eight months after its New Drug Application was submitted to FDA, which is unusual.

Plavix is expected to be a highly prescribed platelet aggregation inhibitor. Its safety when used concurrently with aspirin has not been tested. Since it has a different mechanism of action than aspirin, it is anticipated that physicians will use both drugs concurrently for many patients.

Adverse Reactions. Adverse reactions reported for clopidogrel at 5 percent or more include: indigestion, nausea, vomiting and bleeding. It is contraindicated in patients with any active pathological bleeding disorder such as peptic ulcer disease or intracranial hemorrhage.

Drug Interactions. At the time of its approval, Plavix had not demonstrated any clinically significant drug interactions. It had not been studied in co-administration with warfarin, but it had no noticeable effects on heparin. Aspirin did not increase the platelet inhibition effects of clopidogrel significantly, but clopidogrel did potentiate aspirin somewhat. Clopidogrel increased occult blood (oxidized blood in feces) loss caused by naproxen.

In very high concentrations, clopidogrel inhibits cytochrome P450 (2C9) so there is a possibility it may inhibit the metabolism of some NSAIDs, fluvastatin, phenytoin, tamoxifen, tolbutamide, torsemide and others. The bottom line is that there are no contraindications to concurrent use of these drugs with Plavix, but they should be used cautiously along with patient monitoring.

Indications and Dosing. Plavix is indicated for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease.

The usual adult dosage for Plavix is 75mg once a day with food or on an empty stomach.

Patient Advice. Patients taking Plavix should be advised to take the tablets every day as directed by their physician.

They should not self-medicate with aspirin-containing OTCs without first consulting with their physician. They should be advised to read the labels of OTCs carefully to avoid aspirin- and salicylate-containing products such as Bufferin, Doan's Pills, Excedrin, Pepto-Bismol, etc. They should not take any herbal dietary supplement before determining if it can enhance the effects of anticoagulant drugs.

Patients should be advised that it may take longer than usual to stop bleeding when they take Plavix, and that they should report any unusual bleeding to their physician. They should inform physicians and dentists that they are taking Plavix before any surgery is scheduled and before any new drug is taken.

Eprosartan (Teveten) and Irbesartan (Avapro)

Eprosartan (Tevetan) [Epp-roh-SAHR-ton / TEA-vee-ten] and irbesartan (Avapro) [Erb-ah-SAHR-ton / Ava-PRO] are the third and fourth angiotensin II receptor blockers to be approved in the U.S. They join Cozaar and Diovan in this category.

The initial indication for these drugs is the treatment of hypertension. As with Cozaar and Diovan, however, there is evidence that they are also beneficial in the treatment of congestive heart failure and possibly diabetic nephropathy as well. Avapro is available in 75,150 and 300mg tablets and Teveten comes in 300 and 400mg tablets.

The Disease. Hypertension is the most prevalent cardiovascular disease in the U.S., reportedly affecting 25 percent of adults. Hypertension is a risk factor for atherosclerosis, coronary heart disease and stroke. Long term, uncontrolled hypertension, even if mild, increases the mortality rate.

In spite of the fact that there are nearly a dozen different pharmacologic groups of drugs (many of which are synergistic to each other) available to control hypertension, fewer than one-fourth of currently treated patients receive adequate control of their condition with these agents.

This points to the need for better monitoring of patients and better compliance on their part. The angiotensin II receptor blockers are aimed at improving compliance because of their relatively low order of adverse reactions.

Therapy. As stated above, there are a number of different pharmacologic groups of drugs available for treating hypertension (Table 2). Those of first choice in treating mild, essential hypertension are the thiazide diuretics, beta-adrenergic blockers, calcium channel blockers and angiotensin converting enzyme inhibitors.

The next level of therapy, should a single drug or a combination of the aforementioned classes not be effective in maintaining proper blood pressure, are the alpha-1 specific peripheral adrenergic blockers, the alpha-2 specific central adrenergic agonists and the various vasodilators such as guanethidine, hydralazine, minoxidil and rauwolfia.

As the names imply, both the angiotensin II receptor (AIIR) blockers and the angiotensin converting enzyme (ACE) inhibitors involve activity with angiotensin in their mechanisms of action. Unlike ACE inhibitors, the AIIR blockers do not inhibit the formation of angiotensin II which is part of the renin-angiotensin-aldosterone (RAA) system. Angiotensin II is the most potent vasoconstrictor produced in the body. Instead, the AIIR blockers reduce angiotensin II-mediated vasoconstriction in the vascular smooth muscle and the release of aldosterone from the adrenal medulla by blocking its receptor sites in these tissues.

Both of these actions of angiotensin II contribute to elevated blood pressure, so blocking angiotensin II at these two receptor sites lowers elevated blood pressure. What differentiates AIIR blockers from ACE inhibitors to large extent is that the former have a more selective action on the specific receptor sites for elevated blood pressure.

Angiotensin II has many activities in the body over and above the regulation of blood pressure. It acts on many organs and body systems including the heart, brain, lungs and liver. It affects the production/blood levels of aldosterone, bradykinin, glucose, HDL cholesterol, prostaglandins, triglycerides and uric acid.

There are at least two subtypes of angiotensin II receptors: angiotensin I (AT1) and angiotensin II (AT2). The ACE inhibitors are nonspecific for these receptors because they inhibit the initial formation of angiotensin II. The AIIR blockers are somewhat specific to the AT receptors which are found in vascular smooth muscle and the aldosterone-producing areas in the adrenal gland. They do not significantly affect the angiotensin receptors in other tissues.

Because of this, it is difficult to differentiate the antihypertensive effects of the ACE inhibitors and AIIR blockers. The difference is in the adverse reactions they cause. With the ACE inhibitors, the most morbid (but very rare) adverse reaction is angioedema. This is a condition of severe subdermic edema (thought to be caused by excessive levels of bradykinin) which can cause intense pain, discoloration and disfigurement of skin, especially in the face.

A more prevalent, less morbid, but extremely annoying adverse reaction to the ACE inhibitors is a dry, persistent cough which many patients will not tolerate. This, too, involves bradykinin.

To review, there is a balance between vasoconstriction and vasodilation in the RAA system which maintains hemostasis in healthy individuals. The vasoconstriction side of the scale involves angiotensin II. The vasodilation side involves bradykinin, a potent vasodilator which is also a part of prostaglandin production.

Angiotensin converting enzyme catalyzes the formation of angiotensin II as well as the breakdown of bradykinin. Therefore, the inhibition of ACE can lead to excessive accumulation of bradykinin by reducing its breakdown. This in turn leads to excessive formation of prostaglandins. Since most of this activity occurs in the lungs, the increased level of prostaglandins irritates respiratory tissue and the body responds by coughing.

Because the AIIR blockers reduce the activity of angiotensin

Table 2
Representative Drugs Used to Treat Hypertension

Thiazides and Thiazide-like Diuretics
- Hydrochlorothiazide
- Indapamide

Beta-Adrenergic Blockers
- Acebutolol (Sectral)
- Atenolol (Tenormin)
- Betaxolol (Kerlone)
- Bisoprolol (Zebeta)
- Carteolol (Cartrol)
- Labetalol (Normodyne, Trandate)
- Metoprolol (Lopressor, Toprol XL)
- Nadolol (Corgard)
- Penbutolol (Levatol)
- Pindolol (Visken)
- Propranolol (Inderal)
- Timolol (Blocadren)

Angiotensin Converting Enzyme Inhibitors
- Benazepril (Lotensin)
- Captopril (Capoten)
- Enalapril (Vasotec)
- Fosinopril (Monopril)
- Lisinopril (Prinivil, Zestril)
- Quinapril (Accupril)
- Ramipril (Altace)
- Moexipril (Univasc)
- Trandolapril (Mavik)

Postsynaptic Alpha-1 Adrenergic Blockers
- Doxazosin (Cardura)
- Prazosin (Minipress)
- Terazosin (Hytrin)

Arteriole Vasodilators
- Hydralazine (Apresoline)
- Minoxidil (Loniten)

Loop Diuretics
- Bumetanide (Bumex)
- Furosemide (Lasix)
- Torsemide (Demadex)

Calcium Channel Blockers
- Amlodipine (Norvasc)
- Diltiazem (Cardizem CD) (Dilacor XR)
- Felodipine (Plendil)
- Isradipine (DynaCirc)
- Nicardipine (Cardene)
- Nifedipine (Procarida XL) (Adalat CC)
- Verapamil (Calan SR, Verelan, Covera HS)

Angiotensin II Receptor Blockers
- Irbesartan (Avapro)
- Eprosartan (Teveten)
- Losartan (Cozaar)
- Valsartan (Diovan)

Central Acting Alpha-2 Adrenergic Stimulators
- Clonidine (Catapres)
- Guanabenz (Wytensin)
- Guanfacine (Tenex)
- Methyldopa (Aldomet)

Peripheral Catecholamine Depleters
- Guanadrel (Hylorel)
- Guanethidine (Ismelin)
- Rauwolfia (Reserpine)

II at its receptors in the vascular smooth muscle and adrenal medulla, they do not affect bradykinin levels. Therefore, they do not cause the annoying cough and are more acceptable than the ACE inhibitors.

Regarding their place in the market, the original AIIR blocker (Cozaar) did not have as immediate an impact as some authorities anticipated. However, since its release, sales have steadily increased. Its current position is in the top 100 drugs dispensed, and its combination product containing hydrochlorothiazide has reached the top 200 list this past year.

Adverse Reactions. The AIIR blockers are well tolerated with no adverse reactions reported at 5 percent or more, and none significantly higher than that seen in patients receiving the placebo. For example, in 5000 patients in the irbesartan trials, only 3.4 percent withdrew due to unacceptable adverse reactions. In the placebo-treated group, 4.5 percent dropped out due to unpleasant adverse reactions. A similar outcome was seen with Cozaar.

This class of drugs (including Cozaar and Diovan) has the same boxed warning about pregnancy as the ACE inhibitors, even though they were not tested in pregnant women. All drugs affecting the RAA system directly must carry the following boxed warning in their professional labeling (package insert):

> "WARNING: USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death in the developing fetus. When pregnancy is detected (drug name) should be discontinued as soon as possible. See WARNINGS: Fetal/Neonatal Morbidity and Mortality."

Drug Interactions. No significant drug interactions were reported in clinical trials for these two drugs.

Indications and Dosage. Both Avapro and Teveten are indicated for treating mild to moderate hypertension. The usual adult dose for Avapro is 150mg once a day with or without food. The usual adult dose of Teveten is 300mg once a day with or without food.

Patient Advice. Patients taking Avapro or Teveten should be advised to take the tablets every day as directed by their physician. Some patients (rarely) experience lightheadedness and faintness. If this occurs, they should be careful driving or operating hazardous equipment or standing too quickly after lying or sitting down.

Patients should not self-medicate with OTC nasal decongestants (ephedrine, pseudoephedrine, phenylpropanolamine) or appetite supressants containing phenylpropanolamine without first checking with their doctor. They should not take any herbal dietary supplement before determining if it can enhance the effects of antihypertensive drugs.

Women Respond To Washington Emergency Contraception Project

The women in Washington State have responded overwhelmingly to the Washington State Emergency Contraception Pharmacist Pilot Project, started in February 1998.

PATH (Program for Appropriate Technology in Health) initiated the Project with four other collaborating institutions in an effort to make emergency contraceptive pills (ECPs) more readily available to women in Washington. Collaborative drug therapy agreements between a pharmacist and prescribing clinician enable the pharmacist to prescribe ECPs directly to women in need. Therefore, women may go straight to the pharmacy without first arranging a visit to a doctor or clinic. Since ECPs must be taken within 72 hours of unprotected intercourse, easy access is critical to successful use. Washington is the first and only state where pharmacists are dispensing ECPs directly to women. By mid-summer, more than 500 pharmacists had completed the training required by the Project to provide the service.

Currently, more than 120 pharmacies are participating in the projects. These pharmacies wrote and filled more than 4800 prescriptions for ECPs in the first seven months of service. This represents a significant increase in the number of prescriptions filled. Prior to the Project's launch, one major pharmacy chain reported filling an average of one prescription for ECPs per week. Since the Project launch, that number has increased to an average of 61 per week.

The University of Washington, one of the Project Collaborators, is surveying women who had ECPs prescribed by a pharmacist to evaluate their satisfaction with this service. In surveys collected and analyzed from the first two months of the Project, women rated their interaction with the pharmacist very high. In addition, 50 percent reported that they obtained ECPs on a weekend or after 6 p.m. on a week night, times when they would not normally have been able to see their physician. Also, 42 percent reported that if they had not received ECPs directly from a pharmacist they would have taken no action and would have waited to see if they were pregnant. An additional 15 percent of women didn't know what they would have done if they could not have gone straight to the pharmacy.

The Project's success has not gone unnoticed. Other states are looking at the program. Even other countries are using the Washington State project as an example to help change public policy. In recent discussions with Parliament, physicians' groups and Schering Health Care Ltd., a European ECP manufacturer, the Birth Control Trust of the United Kingdom presented the Washington State Project as a model approach to increase ECP access and reduce unintended pregnancy. As a result, Schering agreed to allow United Kingdom pharmacists to directly prescribe its ECP product, breaking a deadlock that had existed since 1994 when the company announced that it would withdraw its ECP product if it were designated for OTC sale.

The Washington State Project, funded by the David and Lucile Packard Foundation, is a collaboration among PATH, Washington State Pharmacists Association, University of Washington Department of Pharmacy, Washington State Board of Pharmacy and Elgin DDB. PATH also has established a Project Advisory committee that includes legislators, physicians and individuals from various Seattle-area health, pharmacy, insurance and legal organizations.

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Washington State Project At a Glance

Pharmacy Participation

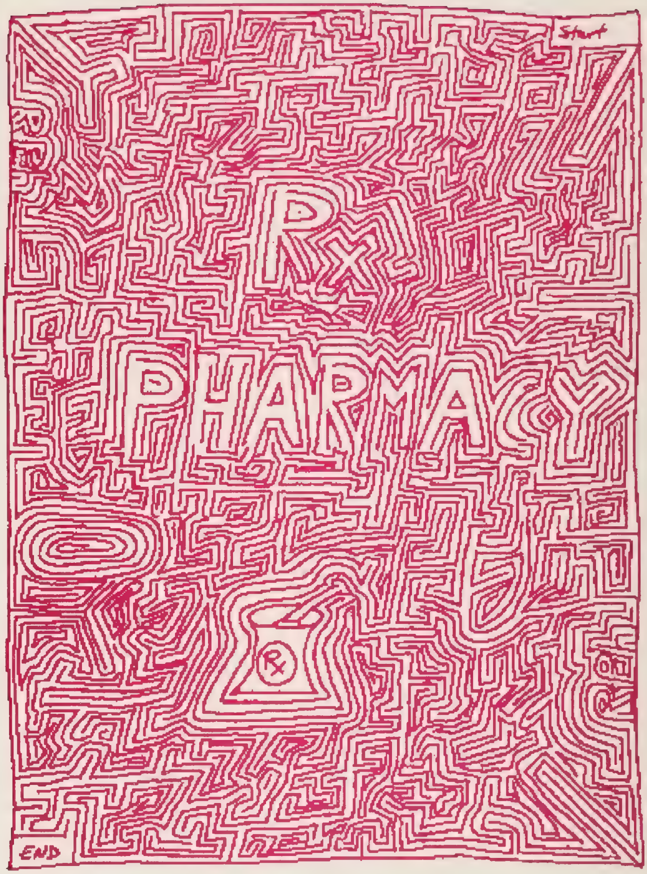
- More than 4,800 prescriptions for emergency contraceptive pills (ECPs) were written and filled by pharmacists in the first seven months of service.
- There are currently more than 120 pharmacies in the state participating in the Project.
- More than 500 pharmacists have completed the required training to prescribe ECPs.

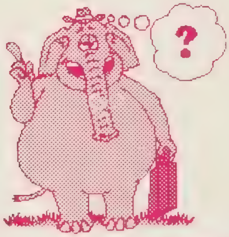
Response to Hotline

- Calls from Washington State to the Emergency Contraception Hotline (1-888-Not-2-Late) increased tenfold to an average of 1,160 per month during the Project's first four months. Prior to the Project's launch, calls from Washington State averaged about 110 per month.

User Survey Results

- 50 percent of women said that they obtained emergency contraception on a weekend or after 6 p.m. on a week night.
- 42 percent of women reported that if they had not received ECPs directly from a pharmacist they would have taken no action and would have waited to see if they were pregnant.
- 85 percent of women had never used ECPs before.
- 56 percent of women reported contraceptive failure.
- 45 percent of women reported learning through the media that they could obtain ECPs directly from a pharmacist.





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This month's questions are taken from the article on "Patient Counseling: New Drugs of 1998: Plavix, Avapro and Teveten." Circle your answers to the following questions and mail the entire page to Maryland Pharmacists CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $10.00). The completed quiz for this issue must be received by 9/15/01. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-98-009-H01

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1. Plavix acts by:
   a. directly inhibiting adenosine diphosphate function.
   b. inhibiting the formation of leukotrienes.
   c. suppressing the formation of prostaglandins.
   d. inhibiting platelet cyclooxygenase.

2. The platelet aggregation inhibitor that should NOT be administered concurrently with Plavix because it has the same mechanism of action is:
   a. aspirin.
   b. dipyridamole.
   c. ticlopidine.
   d. warfarin.

3. The two organs that are most affected by blood clot-initiated tissue necrosis are the:
   a. intestine and spleen.
   b. brain and heart.
   c. kidney and lungs.
   d. liver and spleen.

4. The component of the permanent clot formation mechanism that is insoluble and precipitates to adhere to the hemostatic plug is:
   a. fibrin.
   b. fibrinogen.
   c. plasmin.
   d. plasminogen.

5. The claimed advantage of clopidogrel over ticlopidine is that clopidogrel does not:
   a. inhibit adenosine diphosphate from binding to its receptor sites.
   b. induce adverse hematologic reactions or gastrointestinal upset.
   c. affect the hemostatic plug or the formation of the permanent clot.
   d. inhibit the ability of fibrinogen to induce platelet aggregation.

6. Aspirin prevents platelet aggregation by:
   a. directly inhibiting adenosine diphosphate function.
   b. inhibiting the formation of leukotrienes.
   c. suppressing the formation of prostaglandins.
   d. inhibiting platelet cyclooxygenase.

7. Patients taking Plavix should be advised NOT to self-medicate with which of the following OTCs without consulting their physician?
   a. Diphenhydramine
   b. Pseudoephedrine
   c. Aspirin
   d. Dextromethorphan

8. The previously available product that is most similar therapeutically to Teveten is:
   a. Cozaar.
   b. Mevacor.
   c. Ticlid.
   d. Motrin.

9. The endogenously produced substance that is most involved in the activity of Avapro is:
   a. adenosine diphosphate.
   b. angiotensin.
   c. pepsinogen.
   d. serotonin.

10. The boxed warning for Avapro and Teveten refers to:
    a. heart disease.
    b. liver disorders.
    c. blood dyscrasias.
    d. pregnancy.

Communication

A key element in patient-focused care

Communication has been the emphasis of themes used over recent years during National Pharmacy Week as the industry strives to educate the general population about the current evolution of the field to patient-focused care.

The American Pharmaceutical Association's 1998 slogan of *Communicate to Stay Healthy - Talk with Your Pharmacist* continues to direct attention on the role of the pharmacist as a valuable health care resource and an integral part of a heathy lifestyle. And, since the public is encouraged to develop a relationship with a regular pharmacist, professionals in the industry must assess their abilities to communicate effectively with patients.

Fortunately, effective communication is a learned behavior. The more you practice, the more you will perfect new skills in the various components of communication such as facts, emotions, tone, nonverbal, and nonjudgmental assessment.

"If I were mentoring a pharmacy student today, I would focus on several key areas including patient assessment and communication skills," states Roy Mock, R.Ph., Patient-Focused Care Pharmacist at the City of Hope-Samaritan Bone Marrow Transplantation Program.

"Besides the need to interact with the patients, we must focus on learning the language of physicians. I personally found the training in this skill during the *Patient Focused Care Certificate Program* to be invaluable. The doctors now look at me as a contributing member of the health care team because I speak their language."

Since relationships are built over time, it is advisable for patients to establish a rapport with one pharmacy. Not only can pertinent medical information be readily updated and available on the computer, the pharmacy staff can also develop a personalized and trusting alliance which encourages positive outcomes for the patient's quality of life.

"Besides talking the physicians' language, we must remember to talk the *patients'* language," remarked Ruth Demar of American Pharmaceutical Services, and President-Elect of the APA.

"We need to be counseling the patient not the prescriptions. Instead of simply reading the instruction sheet, demonstrate the value of the pharmacist's knowledge by explaining to the patient the important points about the medication and drug therapy program. This will also justify the reimbursement cost to the payors."

Kathleen Snow, R.Ph., a staff pharmacist in a retail setting, recognizes how important it is to get "a feel" for each patient so that she can personalize her service to the individual.

"In order to take a patient-focused care role, I need to gather data and analyze the facts in order to make sure that the patient is receiving optimum care," explained Kathleen. "I want to help them, so I encourage questions and reassure them as I counsel them. For pharmacy students, it's important to remember 'not to be afraid' to communicate."

Nonverbal Communication: The Silent Language

Tone, inflection, and facial expressions account for 93% of a message; the actual words only account for 7%. The key components of nonverbal communication include:

- eye contact
- body posture
- distance/physical contact
- gestures
- dress/grooming
- facial expression
- vocal tone, inflection, volume
- fluency
- timing

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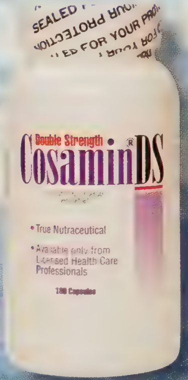
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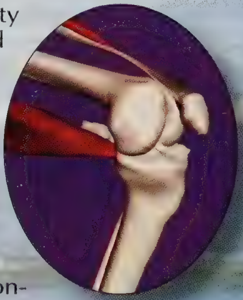

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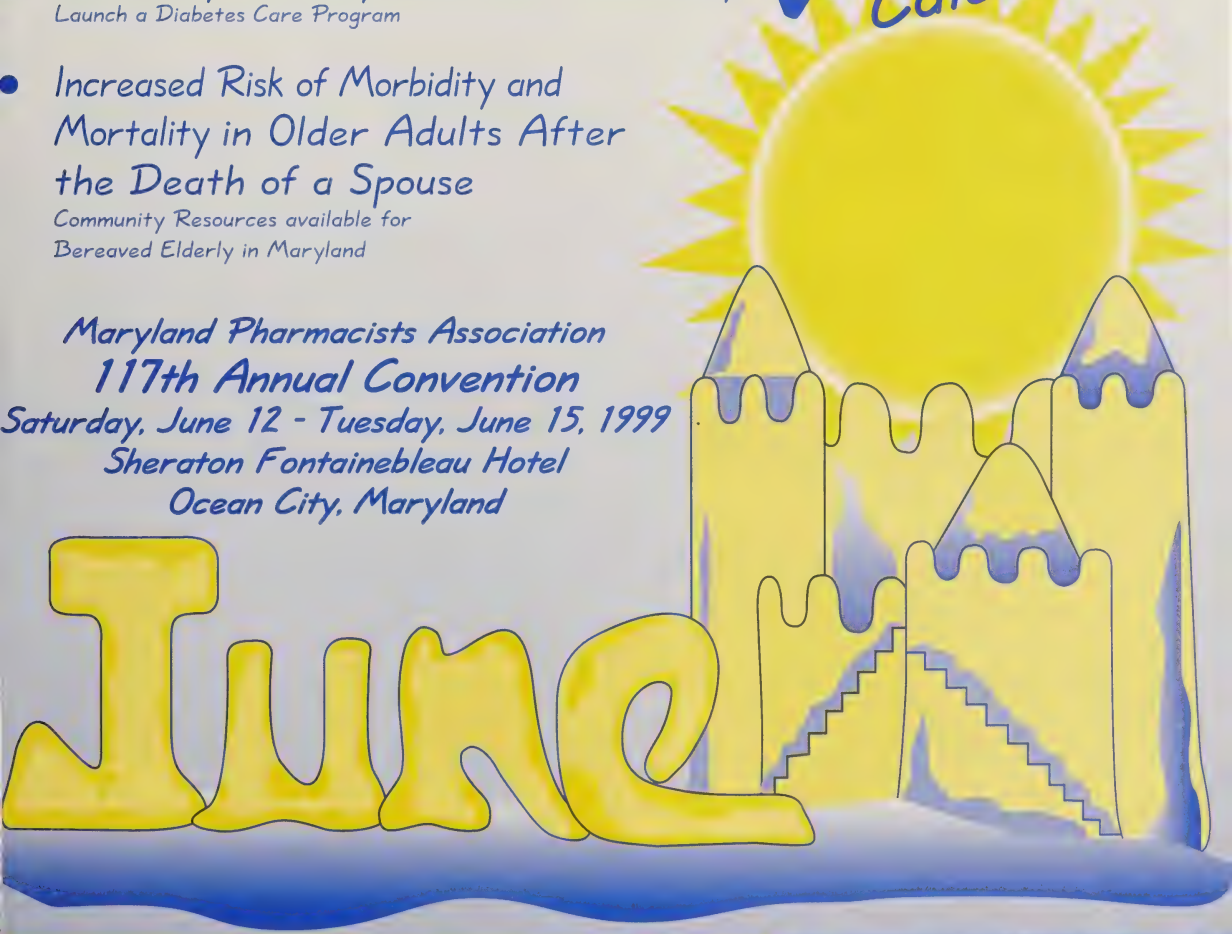
MARYLAND
Pharmacist

VOLUME 75, NO. 2

- President's Commentary
  Pharmacy in the 21st Century!
- University of Maryland, Giant Pharmacy
  Launch a Diabetes Care Program
- Increased Risk of Morbidity and Mortality in Older Adults After the Death of a Spouse
  Community Resources available for Bereaved Elderly in Maryland

✓ Mark Your Calendar

Maryland Pharmacists Association
117th Annual Convention
Saturday, June 12 - Tuesday, June 15, 1999
Sheraton Fontainebleau Hotel
Ocean City, Maryland



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Maryland Pharmacist

The Official Publication of the Maryland Pharmacists Association

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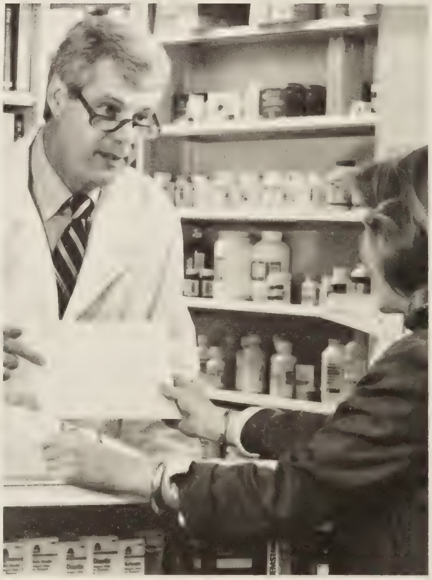

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President's Commentary

Gerard A. Herpel, P.D.

Pharmacy in the 21st Century!

- *Will the pharmacist have a future in pharmacy?*
- *Will the practice of pharmacy be totally automated?*
- *Will the community pharmacies still be on the corner or in the local shopping center?*
- *Will we even need pharmacists to dispense medication or educate patients on the drugs they are using?*
- *Will the personal/professional relationship that a pharmacist has with their patients be obsolete?*
- *Will there even be a need for pharmacists?*

I hope I struck a nerve with the question, "*Will there even be a need for pharmacists?*" Robotics can fill more prescriptions per hour, with a smaller error rate, and don't require the vacation pay or other benefits that human pharmacists demand. So, why even have a pharmacist behind the counter?

A patient can go on the Internet to one of the many pharmacy sites where they get advice, treatment options, and look up the drug interactions of the medications they take. All this and you can order your prescriptions and vitamins with the click of the mouse.

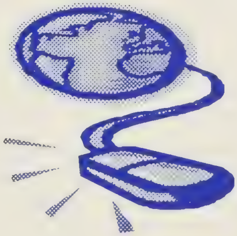
However, both scenarios are missing one key ingredient: the one-on-one personal/professional relationship that pharmacists have with their patients that are seen every day, every week, every month. If we can continue to fulfill this personal need there will always be the community pharmacy.

Still, many of us still need to change our thought process. The best starting place is remembering that we are professionals. Being a professional is a twenty-four hour, seven day a week proposition. We are required to continue our education every year; we are held to a higher standard in own work habits and life than is the general public; and we are licensed and regulated by the state and federal governments.

It is insanity that many pharmacists are apathetic toward their profession and are unconcerned about protecting their livelihood; that joining their state association is not worth the $15 to $20 a month it costs. Maybe someday legislation will pass that will replace pharmacists dispensing with robots, and technicians will fill the supply hoppers. A patient will walk up to the refill machine, press in their prescription number, and just like a soda machine, out pops their 30 tablets of Accupril 10 mg with a patient education leaflet. Y2K is less than 300 days away.

My tenure as President is coming to a close, and our fight for our profession will continue. In the ever changing health care system, as other professions ask for dispensing rights and pharmacists across the country achieve a practice act worthy of this profession, the Maryland Pharmacists Association will always be in the forefront of professional matters.

I would like to take this opportunity to thank you for allowing me to serve you. It has been exciting and rewarding.



Director's Column

Howard R. Schiff, P.D.
Executive Director

Prescription Drug Benefits

- ***Have your patients become more upset with higher copays on their prescription plans?***
- ***Have you seen so called "open" formularies cause you to jump through hoops for non-formulary drugs?***
- ***Have you been assured by a patient that their health plan covers brand only to find that upon adjudication that it does not or does with an increased copay, only to have the patient ask to change the script to the "genetic?"***

Rising prescription benefit costs are increasingly becoming a problem for managed care organizations. The Health Care Access and Cost Commission (HCACC) has formed a Prescription Drug Advisory Committee. HCACC fears prescription benefit plan increases will take the cost above the 12.7% of the average Maryland wage statutory limit for the small group market insurance plans.

Recently, the Maryland Insurance Administration (MIA) held a public hearing on escalating premiums. Every entity from PCS to HMOs, and CareFirst (formerly Blue Cross/Blue Shield) expects double digit premium increases on the drug benefit. They cite everything from new products to utilization increases, direct to consumer advertising, and an aging population.

The rise in prescription drug benefit costs stands out because it is presented as a rider on health plans. The fact that falling hospitalization costs can be related to increased prescription usage is noted, but protestations that drug coverage should be included in the overall cost falls on deaf ears.

Medstat, an independent consultant group for health care purchasers, government agencies, managed care and insurance organizations, and healthcare providers, conducted two studies to evaluate whether increased pharmaceutical expenditures ultimately saved on overall cost. In one study use of non-sedating antihistamines in place of sedating OTC antihistamines was estimated to save businesses between $2.4 million and $4.6 billion from increased productivity. Another study showed the median total direct health care costs of using generic tricyclics was $3.7 mil. compared to $3.6 mil. for Paxil, $3.5 mil. for Zoloft, and $3.5 mil. for Prozac.

Access to non-formulary medications has been addressed by several bills in the state legislature. The Governor's health care initiative has non-formulary drug coverage. The fact is that there is a public demand for prescription coverage which includes medications which may or may not be formulary. Generally, the public does not know the cost of prescription medication until they have to pay for it. As the bearer of bad news, you then become the "bad" guy.

Where do we go from here? CareFirst said that by the year 2005 prescription drug costs will take more of the health dollar than does hospital cost. The commissions must look beyond the cost of the drugs alone and realize that a good prescription plan does not end when the patient receives his or her medication. Drug related problems occur in both the short term and the long term. It is obvious that the pharmacist's talents are not being utilized. The most qualified and accessible professional able to handle encountered or likely to be encountered drug related problems. There are studies that show drug related problems cost $76 billion a year, an enormous expense compared to the $94 billion PCS quoted at the MIA hearing as the annual national prescription drug expense. Perhaps a health report card to measure the insurer's effort to assure compliance or adherence to medication regimens is in order. We recommend compensated pharmacist intervention for those situations in which patients are at risk of inappropriate or less than optimal pharmaceutical therapy. We have so much more to offer, why not here and now?

TOXICITY OF DIET DRUGS

Wendy Klein-Schwartz, Pharm.D., M.P.H.
Coordinator of Research and Education
Maryland Poison Center

Obesity is a significant public health problem in the U.S. It is estimated that 33% of the adult population is overweight, with 14% classified as severely overweight. A complex, multi-factorial disease, obesity is linked to many comorbidities including coronary heart disease, stroke, hypertenion, diabetes mellitus, gout and others. Nonpharmacologic treatments usually include diet, behavior modification and physical activity. Americans spend over 33 billion dollars a year on weight-reducing products.

Fenfluramine and dexfenfluramine were withdrawn from the market in 1997 after being implicated in the development of valvular heart disease.

Appetite suppressant drugs are indicated for individuals at risk for obesity related comorbidities and should be part of a comprehensive weight loss plan. Amphetamine and dexamphetamine were the first appetite suppressant drugs on the market but are no longer used because their marked central stimulant and euphoriant properties led to high abuse potential. The prescription noradrenergic drugs currently approved for the management of obesity are chemically and pharmacologically related to the amphetamines and include benzphetamine, phendimetrazine, diethylpropion, mazindol and phentermine. In therapeutic doses, these drugs increase alertness and sense of well being, but can also result in irritability, nervousness, insomnia, hypertension and tachycardia. With an overdose, these drugs can produce agitation, hyperactivity, confusion, tremor, hyperreflexia, delirium, convulsions and coma. Cardiac toxicity includes arrhythmias, hypertension, and circulatory collapse. Other manifestations of toxicity include mydriasis, diaphoresis, fever, and rhabdomyolysis, which can progress to accuse renal failure. In addition to providing supportive care and GI decontamination with activated charcoal, benzodiazepines should be administered for CNS toxicity, lidocaine for ventricular arrhythmias and nitroprusside or phentolamine for marked hypertension. Initial management of tachyarrhythmias includes administration of oxygen and benzodiazepines to sedate the patient. Pharmacologic intervention with esmolol or labetalol may be required but can worsen hypertension from unopposed alpha adrenergic activity. Fever is treated with external cooling including tepid sponge bath and fan. Controlling associated agitation, psychosis and seizures will also help lower body temperature.

Serotonergic drugs such as fenfluramine, dexfenfluramine and fluoxetine have also been used to suppress appetite. Fenfluramine and the noradrenergic drug phentermine were commonly prescribed together in the combination known as "Fen-Phen". Fenfluramine and dexfenfluramine were very popular diet drugs until September 1997 when they were withdrawn from the market because of their implication in the development of valvular heart disease. Of 113 cases of valvular heart disease in individuals on either fenfluramine or dexfenfluramine reported to the FDA, 98% were women with a median age of 44 years and the majority had been on the combination "Fen-Phen". Surveys found a prevalence of valvular heart disease of 32.8% in individuals using these diet drugs, with aortic regurgitation more common than mitral regurgitation.

Fluoxetine (Prozac®), a serotonin reuptake inhibitor used in the treatment of depression, was noted to cause weight loss in clinical trials.

"Serotonin syndrome" can occur with agents such as Prozac, either by themselves, or more commonly, due to drug interactions.

Although not approved for the management of obesity, its popularity has increased now that fenfluramine and dexfenfluramine are no longer available. Prescribed alone or in combination with phentermine (known as 'Pro-Phen'), fluoxetine's side effects include drowsiness, insomnia, nausea, diarrhea and dry mouth. Overdoses of fluoxetine are usually not as serious as overdoses with cyclic antidepressants. Agitation, dizziness, tremor, drowsiness, seizures, nausea, vomiting, tachycardia and hypotension are common toxic effects. Fluoxetine can also cause serotonin syndrome, the severe manifestations of which include delirium, hallucinations, mania, seizures, coma, clonus, myoclonus, muscle rigidity, hyperthermia, hypertension or hypotension and tachycardia. Serotonin syndrome can occur with serotonergic agents by themselves but is much more commonly the result of an interaction between two drugs with serotonergic properties. Management includes discontinuing the causative agents and providing symptomatic care (including external cooling, paralytic agents, ventilation, anticonvulsants, antihypertensives, benzodiazepines). Serotonin antagonists such as cyproheptadine and methysergide have been used in a few cases.

Sibutramine (Meridia®), the newest prescription diet drug on the market, is structurally related to amphetamine. Taken once daily, sibutramine inhibits the reuptake of norepinephrine, serotonin and possibly dopamine; it should not be taken concomitantly with MAO inhibitors or SSRIs. Common side effects include insomnia, tachycardia, hypertention and dry mouth. Orlistat (Xenical®) has not yet been approved by the FDA but is expected to be approved in 1999. A lipase inhibitor, orlistat decreases dietary fat absorption and increases fecal fat excretion. Side effects include nausea, abdominal cramps, diarrhea, and fecal incontinence. There are also concerns about a possible association with breast cancer. Phenylpropanolamine, a nonprescription diet drug, can cause nervousness, insomnia, dizziness, diaphoresis, anxiety, headache and hypertension. There are case reports of serious adverse effects associated with phenylpropanolamine including marked hypertension, stroke intracerebral hemorrhage, seizures, cardiac arrhythmias and acute interstitial nephritis. The doses associated with these severe adverse effects are highly variable, although usually higher than the recommended dosage.

> ***"Herbal Fen-Phen" is a weight loss alternative that contains ephedra and St. John's Wort.***

A weight loss combination that is marked as a natural herbal alternative and is sometimes called 'Herbal Fen-Phen' contains ephedra (Ma Huang) and St. John's Wort (Hypericum perforatum). The main active ingredient in Ma Huang is ephedrine, with pseudoephedrine and norpseudoephedrine present in smaller amounts. Adverse effects range from hypertention, arrhythmias, insomnia, headache, neverousness and tremors to seizures, myocardia infarctions, strokes and death. The active ingredient in St. John's Wort is hypericin. Dry mouth, dizziness, constipation, other GI symptoms and confusion have been reported with its use. Other concerns regard the potency and purity of these products since amounts vary in different parts of the plant and at different times of year and may depend on growth conditions.

There are many products being promoted through the Internet, print ads and health food stores for which there is no evidence of efficacy in the management of obesity. Examples include glucomannan tablets, which are reported to produce a feeling of fullness, ipecac syrup to purge after meals, chromium picolinate to improve glucose tolerance and promote development of lean body mass, aminophylline creams for topical application to thighs and stomach, yohibe creams and yohimbine containing tablets to block alpha-2 adrenergic receptors resulting in thermogenic properties which release fat, and the blue-green algae Spirulina which claims to be effective not only for appetite suppression, but also for diabetes, hepatitis, anemia, stress, pancreatitis, cataracts, hair loss and many other conditions. Although not efficacious, some of these products have not been associated with serious adverse effects. Other agents, such as ipecac syrup, have well-documented toxicity with chronic use. New products are coming on this unregulated market every day. It is important for health professionals to query their patients about products purchased outside the traditional health care system and to be vigilant in detecting previously unobserved and/or unreported adverse effects.

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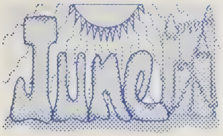
117th Annual Convention

Saturday, June 12 - Tuesday, June 15, 1999
Sheraton Fontainebleau Hotel,
Ocean City, Maryland

Riding a New Wave for Maryland Pharmacy



Join Us

We hope you will enjoy the many educational, professional and social events planned for this year's convention. Come to Oceanfront luxury and enjoy the beauty and excitement that comes with the sunrise, sunset, and the ocean breeze. Escape to where life's a bit more relaxed, more magical, and more romantic.

CE

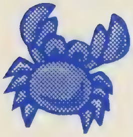
The continuing education programs offered during this year's program cover a wide range of topics. Learn the mysteries of Far East Medicine, the New Age theories from the West Coast, plus other new and exciting topics. Earn up to 19½ contact hours of continuing education.

CPR

Overcome any reluctance to act in emergency situations and to recognize and care for life-threatening respiratory or cardiac emergencies in adults. Be a part of the vital link in the chain of survival to help save lives.

Myers-Briggs

Do you trust your hunches or stick to the facts? Is your motto "work before play" or "enjoy now, work later?" Find a better way to understand yourself, your spouse, co-workers and patients by finding out your Myers-Briggs personality type. This session is open to pharmacists, spouses and children over 16.

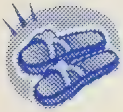


Trade Show & Job Fair

Connect to your future. Visit the exhibits on Monday, June 14. *During lunch*, you will find displays of the latest innovative products and services. You may also find if the grass is greener on the other side. Meet with prospective employers in a casual, nonintimidating setting (with no business suits or appointments.) Following the Trade Show & Job Fair is a session on resume writing and interviewing skills.

Social Events

Enjoy the laid-back, casual atmosphere of the beach and take part in the President's Reception, Crab Feast, and Awards Reception and Banquet. Enjoy the best that Maryland has to offer—all in Ocean City. Have fun and relax with friends and family. There will be lots of great food!

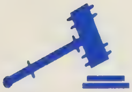


What to Wear

Casual attire is appropriate for all education sessions and for evening social activities. The Awards Reception and Banquet is business attire.

Raffle

Better than the Maryland Lottery—betting on the horses at Pimlico—the slots at Atlantic City, the MPhA Raffle is your best chance to win two Continental Airline tickets to anywhere in the contiguous United States and support the Association at the same time. You do not need to be present to win. Proceeds will benefit the MPhA Foundation.



Pharm Auction

Come join the fun—a real, live auction featuring our own President, Jerry Herpel, as auctioneer. There will be pharmacy memorabilia from the Kelly Building as well as other wonderful items. The excitement and bidding will take place before the Annual Banquet on *Monday, June 14*. Proceeds will benefit the MPhA Foundation.

Advance Registration

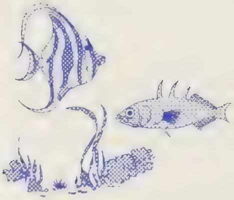
Please complete the registration form included in this brochure. Type or print clearly and return the form with your check or credit card information to: **MPhA Annual Convention, 650 W. Lombard Street, Baltimore, MD 21201-1572.** If you are paying with a credit card, you may FAX your registration to MPhA at 410-727-2253. Register before the deadline and save the $40 on-site fee. ***The deadline for Advance Registration is Friday, May 28, 1999.***

On-site Registration

Registration forms received after the advance registration deadline will not be processed. You will need to register when you arrive at the Sheraton and add the $40 on-site fee.

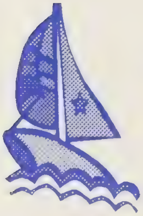
Registration Fees

Full pharmacist registration fee includes all breakfasts, admission to all educational sessions, beverage breaks, lunches and all evening events. ***Full spouse/guest registration*** fee includes all breakfasts, admission to Myers-Briggs and all evening events. *(Fee does not includes lunches or the Trade Show & Job Fair.)* ***Child registration*** fee includes all breakfasts, Myers-Briggs for children over 16 years old, and the President's Reception on Saturday evening. *(Fee does not includes lunches, the Trade Show & Job Fair, Crab Feast or Awards Reception/Banquet.)* ***Student registration*** fee includes all breakfasts, admission to all educational sessions and the President's Reception on Saturday evening. *(Fee does not include lunches, the Trade Show & Job Fair, the Crab Feast or Awards Reception/Banquet.)* ***Daily registration*** fee includes breakfast, admission to all education sessions, beverage breaks, and lunch for that day. If you have any questions about the program and/or registration, please contact the Maryland Pharmacists Association at 410-727-0746 or toll-free in Maryland 800-833-7587.



Registration Cancellation

To cancel your registration and receive a refund, a written request must be received by Friday, May 28, 1999. Cancellation requests received by this date will be processed and a refund issued less a $25 processing fee. Please allow 4-6 weeks for processing. All requests received after Friday, May 28, 1999, will mandate a 100% forfeiture of monies paid.



Hotel Accommodations

The Sheraton Fontainebleau has kept the *same discounted rates as last year.* To reserve your room, call the Sheraton directly at 800-638-2100. You must tell the reservation agent you are with the Maryland Pharmacists Association to receive the special rate. A deposit equal to one night's stay is required to hold the reservation. ***The deadline is Tuesday, May 11, 1999.***

Hotel Cancellation

Reservation cancellations must be made 72 hours prior to scheduled arrival to avoid a full room rate "No Show" charge. If you cancel, you must have a cancellation number to receive a refund. If you stay more than one night and change your length of stay, you must notify the hotel at or before check-in to avoid an early check-out fee of $125.

Room Rates

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Triple	$154
Quad	$169
Executive King	$159
Studio King	$169
Cabana	$275

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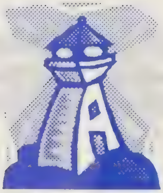

Special Needs

If you require special accommodations or meals to participate in this educational program, please provide written information about your requirements to the Maryland Pharmacists Association at least ten (10) business days in advance of the meeting.

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MPhA 117th Annual Convention • Sheraton Fontainebleau Hotel, Ocean City, Maryland • June 12-15, 1999

Registration Form

Deadline: Friday, May 28, 1999

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☐ ***Please consider me for appointment as an At-Large Delegate at the House of Delegates Meetings.***

Spouse/Guest Names ______________________________

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Full Registration	☐	MPhA Member		($185)	$ ______
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	☐	Non-Member Pharmacist *		($285)	______
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(Check all that apply)		☐ Sat ☐ Sun ☐ Mon ☐ Tue			
On-Site Fee	☐	Forms received after 5/28/99 must include the $40 on-site fee			$ ______
Extra Event Tickets *Crab Feast*	☐	Adults/Pharmacy Students	______ @	($35)	$ ______
	☐	Child Under 12	______ @	($15)	______
Awards Reception and Banquet	☐	Adults/Pharmacy Students	______ @	($45)	$ ______
	☐	Child Under 12	______ @	($20)	______
House of Delegates	☐	Lunch	______ @	($15)	______
Trade Show & Job Fair	☐	Lunch	______ @	($15)	______
CPR	☐	Adults/Pharmacy Students	______ @	($20)	______
Total Fee					**$ ______**

So that we may better plan, please indicate the events you expect to attend:

	Yes	No	Number
Saturday, June 12			
President's Reception	☐	☐	______
Sunday, June 13			
Breakfast	☐	☐	______
Lunch	☐	☐	______
Crab Feast	☐	☐	______
Monday, June 14			
Breakfast	☐	☐	______
Lunch	☐	☐	______
Awards Banquet	☐	☐	______
Tuesday, June 15			
Breakfast	☐	☐	______

ADA Compliance:

Please attach a written description of the dietary or special assistance needed. MPhA cannot assure the availability of appropriate accommodations without being notified ten (10) business days in advance of the meeting.

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Schedule at a Glance

Saturday, June 12

12:00 - 5:00	Registration
1:00 - 1:50	"Adrenergic Alopecia—The Pharmacists Role in Helping Consumers"
2:00 - 2:50	"Senior Care Pharmacy: Today's Opportunity, Tomorrow's Imperative"
3:00 - 3:50	"New Treatments in Osteoarthritis and Rheumatoid Arthritis"
4:00 - 4:50	"Role of Cytochrome p450 isoenzymes"
8:00 - 10:00	President's Reception

Sunday, June 13

7:00 - 5:00	Registration
7:00 - 9:00	Continental Breakfast
8:00 - 9:50	"Prescription for Temperament" Myers-Briggs Type Indicator
10:00 - 11:50	"Fundamentals of Chinese Herbology"
12:00 - 1:30	Lunch - House of Delegates
1:30 - 2:20	"Management of GERD—A Pharmacists Perspective"
2:30 - 5:00	"Women's Health Issues—A Natural Approach"
6:30 - 9:00	Crab Feast

Monday, June 14

7:00 - 5:00	Registration
7:00 - 9:00	Continental Breakfast
7:00 - 9:00	Trustee Breakfast - Meeting
8:00 - 8:50	"Schering Report XXI"
8:00 - 12:00	CPR
9:00 - 12:00	"Ayurvedic Medicine: From 'Alternative' to 'Integrated'; The Scientific Validation of Traditional Herbal Remedies"
12:00 - 2:00	Lunch - Trade Show & Job Fair
2:00 - 2:50	"Getting the Job: Effective Resumes & Interviewing Skills"
3:00 - 5:00	House of Delegates
7:00 - 8:00	Auction & Banquet Reception
8:00 - 10:30	Awards Banquet

Tuesday, June 15

7:00 - 11:00	Registration
7:00 - 9:00	Continental Breakfast
8:00 - 8:50	Financial Management
9:00 - 9:50	Pain Mangement
10:00 - 10:50	Obesity

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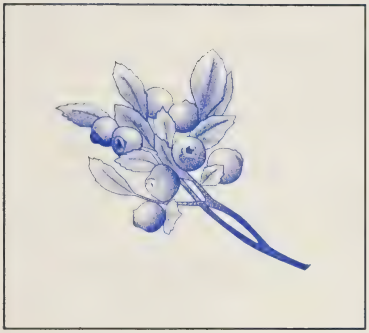

Did British Royal Air Force pilots flying night bombing raids against Hitler during WWII know that eating bilberry jam before their missions would improve their night vision—or did they discover it coincidently? No one knows for sure, but this anecdote is one of the most famous linking bilberry with good vision and eye care.

In early clinical studies, administration of bilberry extract to healthy subjects resulted in improved nighttime visual acuity, faster adjustment to darkness, and more rapid restoration of visual acuity after exposure to bright light.

Because of its strong affinity for pigmented retinal tissue, bilberry acts inherently to improve blood flow to the retina and the macula (responsible for the eye's adaptation to light), and it supports regeneration of retinal tissue. Bilbeny protects delicate eye structures from free radical damage and can actually stop the progress of certain eye disorders such as cataracts and macular degeneration.

Known also as the European blueberry, whortle-berry, and the huckleberry, bilberry *(Vaccinium myrtillus)* is used extensively today in conventional European medical practice to help prevent and treat eye disorders such as glaucoma, cataracts, night blindness, diabetic retinopathy, macular degeneration, and retinitis pigmentosa.

Clinical studies conducted over the last 30 years in both humans and animals have confirmed bilberry extract's efficacy in the treatment of eye disease, visual disorders and vascular conditions. For example, a 1981 German study of bilberry extract given to 31 patients with various retinopathies showed stabilized permeability and improved blood flow, particularly in patients with diabetic retinopathy.

The list of potential vascular benefits conferred by bilberry is long: it strengthens capillary walls by collagen fiber cross-linking; reduces capillary breakage and leakiness; increases blood vessel stretch and resistance to enzymatic damage; improves peripheral and microcirculatory blood flow; and decreases permeability of the blood-brain barrier.

Thus, bilberry extract has been used to treat gastric disorders, diabetes (hyperglycemia), and various vascular/circulatory conditions, including varicose veins and excessive bruising.

The active ingredient in bilberries is anthocyanoside, which appears to increase intracellular Vitamin C levels and is an aggressive free radical scavenger. The actions of bilberry are potentiated when taken with other antioxidants such as vitamins A, C, E and gingko biloba.

Vigorously tested, anthocyanosides have not shown toxic effects to date.

To use bilberry extract prophylacticaly or therapeutically, look for a product with an anthocyanoside content based on standardized 25% anthocyanidin, in 80-160 mg capsules, or anthocyanosides (anthocyanidin) in 20-40 mg capsules. Bilberry is also available in liquid extract form.

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A Brief History of Pharmacy

Glancing around a modern pharmacy, it is difficult to believe that the origins of the profession date back almost 5,000 years.

KELLER'S PHARMACY
ALEX. G. KELLER,
Ph.G.
DRUGGIST

Pharmacy in the Western World originated in Egypt as early as 2900 B.C. Ancient Egyptian pharmacy was a well established profession. It was believed to have been organized on two basic levels: the "gatherers and preparers" of drugs, and the "chiefs of fabrication," somewhat like the modern head pharmacist.

Modern pharmacy has many similarities to ancient pharmacy. For example, the "trademarking" of drugs dates from 500 B.C. At that time, on the Mediterranean island of Lemnos, clay tablets were prepared for use as medicine. Each tablet was impressed with an official seal by a priestess and then dried in the sun. Pharmacy "stores" are believed to have originated in Bagdad during the Eighth Century. Until then, medicine and pharmacy were practiced as a single art. For the Western World, it wasn't until the edict of Emperor Frederick II, in 1240 A.D., that pharmacy and medicine were officially separated. Since then, both professions have grown in professional art, scientific knowledge, and experience in their separate, but closely related, spheres.

Although pharmacy and medicine pursue separate disciplines, the modern physician and pharmacist collaborate closely as members of a team devoted to the betterment of your health as well as that of the community.

* * *

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A Weighted Issue

First evidence-based Federal obesity clinical guidelines released

The first Federal guidelines on the identification, evaluation, and treatment of overweight and obesity in adults were released recently by the National Heart, Lung, and Blood Institute (NHLBI), in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

These clinical practice guidelines are designed to help physicians in their care of overweight and obesity, a growing public health problem that affects 97 million American adults—55 percent of the population.

These individuals are at increased risk of illness from hypertension, lipid disorders, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and certain cancers. The total costs attributable to obesity-related disease approaches $100 billion annually.

"Overweight and obesity pose a major public health challenge. The development of these guidelines was a pioneering achievement since they were the first ever developed by the Institute using an evidence-based model and methodology," said NHLBI Director Dr. Claude Lenfant. "This report will be an invaluable clinical tool for any health care professional who works with overweight or obese patients," he added.

The guidelines are based on the most extensive review of the scientific evidence on overweight and obesity conducted to date. The review involved a systematic analysis of the published scientific literature to address 35 key clinical questions on how different treatment strategies affect weight loss and how weight control affects the major risk factors for heart disease and stroke as well as other chronic diseases and conditions.

The guidelines present a new approach for the assessment of overweight and obesity and establish principles of safe and effective weight loss. According to the guidelines, assessment of overweight involves evaluation of three key measures--body mass index (BMI), waist circumference, and a patient's risk factors for diseases and conditions associated with obesity.

The guidelines' definition of overweight is based on research which relates body mass index to risk of death and illness. The 24-member expert panel that developed the guidelines identified overweight as a BMI of 25 to 29.9 and obesity as a BMI of 30 and above, which is consistent with the definitions used in many other countries, and supports the Dietary *Guidelines for Americans* issued in 1995. BMI describes body weight relative to height and is strongly correlated with total body fat content in adults. The BMI numbers apply to both men and women. Some very muscular people may have a high BMI without health risks.

The panel recommends that BMI be determined in all adults. People of normal weights should have their BMI reassessed in 2 years.

"The evidence is solid that the risk for various cardiovascular and other diseases rises significantly when someone's BMI is over 25 and that risk of death increases as the body mass index reaches and surpasses 30," said Dr. F. Xavier Pi Sunyer, chairman of the expert panel and director of the Obesity Research Center, St. Luke's/Roosevelt Hospital Center in New York City.

"The guidelines tell the truth about the risks associated with unhealthy weight. We hope that physicians and the public will take the message seriously and use the guidelines to begin to deal effectively with a difficult problem," asserted Dr. Pi-Sunyer.

According to a new analysis of the National Health and Nutrition Examination Survey (NHANES III), as BMI levels rise, average blood pressure and total cholesterol levels increase and average HDL or good cholesterol levels decrease. Men in the highest obesity category have more than twice the risk of hypertension, high blood cholesterol, or both compared to men of normal weight. Women in the highest obesity category have four times the risk of either or both of these risk factors.

The guidelines recommend weight loss to lower high blood pressure, to lower high total cholesterol and to raise low levels of HDL or good cholesterol, and to lower elevated blood glucose in overweight persons with two or more risk factors and in obese persons. Overweight patients without risk factors should prevent further weight gain, advise the guidelines.

In addition to measuring BMI, health care professionals should evaluate a patient's risk factors, such as elevations in blood pressure or blood cholesterol, or family history of obesity-related disease. At a given level of overweight or obesity, patients with additional risk factors are considered to be at higher risk for health problems, requiring more intensive therapy and modification of any risk factors.

Physicians are also advised to determine waist circumference, which is strongly associated with abdominal fat. Excess abdominal fat is an independent predictor of disease risk. A waist circumference of over 40 inches in men and over 35 inches in women signifies increased risk in those who have a BMI of 25 to 34.9.

According to the guidelines, the most successful strategies for weight loss include calorie reduction, increased physical activity, and behavior therapy designed to improve eating and physical activity habits. Other recommendations include:

- Patients should engage in moderate physical activity, progressing to 30 minutes or more on most or preferably all days of the week.
- Reducing dietary fat alone—without reducing calories--will not produce weight loss. Cutting back on dietary fat can help reduce calories and is heart-healthy.
- The initial goal of treatment should be to reduce body weight by about 10 percent from baseline, an amount that reduces obesity-related risk factors. With success, and if warranted, further wight loss can be attempted.
- A reasonable time line for a 10 percent reduction in body weight is six months of treatment, with a weight loss of 1 to 2 pounds per week.
- Weight-maintenance should be a priority after the first 6 months of weight-loss therapy.
- Physicians should have their patients try lifestyle therapy for at least 6 months before embarking on physician-prescribed drug therapy. Weight loss drugs approved by the FDA for long-term use may be tried as part of a comprehensive weight loss program that includes dietary therapy and physical activity in carefully selected patients (BMI ≥ 30 without additional risk factors, BMI ≥ 27 with two or more risk factors) who have been unable to lose weight or maintain weight loss with conventional non drug therapies. Drug therapy may also be used during the weight maintenance phase of treatment. However, drug safety and effectiveness beyond one year of total treatment have not been established.
- Weight loss surgery is an option for carefully selected patients with clinically severe obesity -- BMI of ≥ 40 or BMI of ≥ 35 with coexisting conditions when less invasive methods have failed and the patient is at high risk for obesity-associated illness. Lifelong medical surveillance after surgery is a necessity.
- Overweight and obese patients who do not wish to lose weight, or are otherwise not candidates for weight loss treatment, should be counseled on strategies to avoid further weight gain.
- Age alone should not preclude weight loss treatment in older adults. A careful evaluation of potential risks and benefits in the individual patient should guide management.

According to NHANES III, the trend in the prevalence of overweight and obesity is upward. The guidelines note that from 1960 to 1994, the prevalence of obesity in adults (BMI ≥ 30) increased from nearly 13 percent to 22.5 percent of the U.S. population, with most of the increase occurring in the 1990s.

"There are several possible reasons for the increase," asserted Karen Donato, coordinator of the Obesity Education Initiative. "When people read labels, they're more likely to notice what's lowfat and healthy, but may not be looking at calories. Also, more people are eating out and portion sizes have increased. Another issue is decreased physical activity. So people are consuming more calories and are less active. It doesn't take much to tip the energy balance," she said.

The upward trend in adult obesity has also been observed in children, notes the report. Since treatment issues surrounding overweight children and adolescents are quite different from the treatment of adults, the panel called for a separate guideline for youth as soon as possible. However, a healthy eating plan and increased physical activity is an important goal for all family members.

With that in mind, the guidelines contain practical information on healthy eating. Based on this material, the NHLBI has developed consumer tips on shopping, eating, and dining out.

The guidelines have been reviewed by 115 health experts at major medical and professional societies. They have been endorsed by the coordinating committees of the National Cholesterol Education Program and the National High Blood Pressure Education Program, the North American Association for the Study of Obesity, the NIDDK Task Force on the Prevention and Treatment of Obesity, and the American Heart Association. These groups represent 54 professional societies, government agencies, and consumer organizations. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults* will be distributed to primary care physicians in the U.S. as well as to other interested health care practitioners. It is available on the NHLBI Web site. Single free copies of the consumer tips referred to above are available by writing to the NHLBI Information Center, P. O. Box 30105, Bethesda, MD 20824-0105.

By Susan Kleppin, R.Ph.

For more information, contact Sue Kleppin, R.Ph.
at the PSW office, 608-827-9200

Obesity is a major public health problem in the United States. In the last two decades alone, the prevalence of obesity among American men and women has increased from 25 to 33 percent, according to data from the National Health and Nutrition Examination Surveys.

While there is agreement about the health risks associated with obesity, there traditionally has not been agreement on its management. A plethora of fad diets, weight loss plans and centers, Web sites, and books on weight management and dieting exist, all professing to be the answer for weight loss. In the medical literature as well, hundreds of articles have been published on obesity and its management.

In May 1995, the Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults was convened by the National Heart, Lung, and Blood Institute's Obesity Education Initiative with the cooperation of the National Institute of Diabetes and Digestive and Kidney Diseases. Their charge was to do a systematic review of the published scientific literature and to determine the most appropriate treatment strategies that would constitute evidence-based clinical guidelines on overweight and obesity. Evidence from approximately 394 randomized controlled trials was considered by the panel.[1] A summary of these recommendations are included in this issue. A copy of the complete expert panel report can be reviewed or downloaded from the Internet. It is available on the NHLBI Website.

Obesity is associated with increased risk of type 2 diabetes, hypertension, cardiovascular disease, gall bladder disease and breast, endometrial and colon cancer, and osteoarthritis.[2] The economic costs of obesity have been documented by several authors. Direct costs attributable to the treatment of the mentioned disease states have been conservatively estimated at $51.6 billion dollars in 1995.[3] Indirect costs were also estimated. These costs represent the value of productivity lost in the workplace, caused by the morbidity and mortality due to disease associated with obesity. These indirect costs are estimated at $47.56 billion; therefore the total economic cost of obesity was estimated to be $99.2 billion in 1995.[4]

It should come as no surprise therefore, that considerable interest exists in the management and treatment of obesity. As a chronic disease, obesity requires long-term treatment. Effective treatment should address all the factors that contribute to unhealthy excess weight gain such as genetics, neurology/physiology, environmental factors, psychological factors, and psycho-social factors.

The degree of obesity is assessed using a measure known as "Body Mass Index" (BMI). To calculate BMI, divide weight (in kg) by height^2 (in meters^2). This number, the patient's waist circumference, and the patient's concomitant risk factors for diseases and conditions associated with obesity are used for evaluation and assessment and determine the recommended treatment.

Pharmacologic treatment of obesity is not recommended by the NIH guidelines unless patients have tried to lose weight or maintain weight loss with conventional nondrug therapies and their BMI ≥ 30 without any risk factors. If the patient has two or more risk factors and a BMI ≥ 27, drug therapy can also be considered. With the voluntary market withdrawal of fenfluramine and dexfenfluramine in September 1997, only one prescription anti-obesity drug remains on the market, with several others in the development pipeline.

Meridia® (sibutramine hydrochloride monohydrate) Capsules Class CIV has been available since February 1998. It is a novel neurotransmitter reuptake inhibitor of norepinephrine and serotonin, that enhances the feeling of satiety (the felling of fullness). Knoll Pharmaceutical Company, the drug's manufacturer, has created the Point of Change™ tailored weight management program for patients on Meridia®. Patients on Meridia® who enroll receive tailored information in the form of newsletters, on diet (including personal menu plans), exercise, and behavior modification. Patients can enroll by calling 1-888-566-5502, through their physicians, or pharmacists. Pharmacists receive $3 for each patient they enroll in the Point of Change program. To register your pharmacy, call Knoll at 1-888-566-5504.

Another drug, orlistat (Xenica®), developed by Roche, has received approval in Europe and Roche is working with the FDA to achieve approval in the US. Orlistat is a drug in a new class of non-systemically acting anti-obesity drugs called lipase inhibitors. It acts in the gastrointestinal tract and prevents the absorption of fat by about 30 percent.

Both orlistat and sibutramine got considerable attention at the Eight International Congress on Obesity, a four day conference held in Paris, August 29-September 3. Medical experts at this conference warned that obesity was rapidly becoming a problem in the developing world as well as industrialized nations and could one day rival smoking in its impact on public health.

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[1] National Institutes of Health. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. Washington DC: US Government Printing Office.

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[3] Wolf AM, Colditz GA. Current estimates of the economic cost of obesity in the United States. Obes Res. 1998 Mar; 6(2): 97-106.

[4] Ibid

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University of Maryland, Giant Pharmacy Launch a Diabetes Care Program

by Christine Stutz

A pilot program run by a University of Maryland School of Pharmacy professor and Giant Food, Inc. offers diabetic patients and their families important education about managing the disease. The private, one-on-one classes are conveniently located in a Patient Care Center adjacent to the pharmacy department of Giant Food, which sponsors the program. The educational sessions follow the recommendations of the American Diabetes Association (ADA).

This new pharmaceutical care initiative, the only one of its kind in Maryland, represents a new trend in pharmacy. Diabetes education programs help prevent complications and reduce overall health care costs. While there are other diabetes programs in Maryland, this is the first one offered in a supermarket pharmacy where pharmaceutical care, nutrition and patient education are combined to provide a comprehensive patient education program, said Magaly Rodriguez de Bittner, PharmD, BCPS, a Certified Diabetes Educator and assistant professor at the School of Pharmacy, who developed the project.

The diabetes care program allows pharmacists to work closely with patients to monitor their medications, teach self-management skills, improve outcomes and to track their progress. The pharmacist consults with the treating physician to share information and develop the best diabetes management plan for each patient.

This initiative is unique because it recognizes the importance of the pharmacist in helping patients manage chronic illnesses. "We are the experts in drug therapy. So who better to talk to patients about medicines?" said Rodriguez de Bittner. Also, while most people see their physician once or twice a year, they see their pharmacist more frequently. It's convenient and may be cost-effective for pharmacists to offer education and follow-up to patients with chronic disease states, she said.

The diabetes education program consists of eight private sessions, each focusing on a specific aspect of the disease. At each session, the patient's progress is measured, useful nutritional and self-management issues are explained and demonstrated. After each session, the patient receives a complimentary packet of related products. Throughout the program, which costs $300, the patient and pharmacist develop self-care goals. Any person with diabetes may request a free 15-minute consultation with a pharmacist at the Giant store.

Since 1995, when she first approached Giant about starting the program, Dr. Rodriguez de Bittner and collegues have trained 570 of Giant's pharmacists in pharmaceutical care and four disease states, including diabetes. In November 1998, Giant's first pharmaceutical care center opened at the Route 40-Rolling Road location in Catonsville. The store was chosen partly because its pharmacy is the busiest in the regional chain, filling some 5,000 prescriptions per week and because of the large number of patients with diabetes who visit the store.

As of March 31, 1999, 48 diabetic patients had received the free consultation. Of those, 14 are currently enrolled in the program. These patients report they are very satisfied with the services thus far and have begun to see improvements in their health. To date, Rodriguez de Bittner has had 100 percent participation and cooperation from treating physicians.

Russell Fair, Giant's vice president of pharmacy operations, said, "Giant is pleased to be in partnership with the University of Maryland to offer this program to provide counseling and education on diabetes to people living with the disease. Our goal is to equip diabetes patients and their families with the education they need to manage the disease."

There are an estimated 16 million diabetics in the United States, Rodriguez de Bittner said, more than half of whom don't yet know they have the disease.

In addition to diabetes, other pharmaceutical care programs in asthma, hyperlipidemia and smoking cessation are expected to be offered at the Patient Care Center in the near future.

A Look Back

Why should preparations of cannabis in particular be assayed? Cannabis is very easily rendered inert by heating. Why should a dog always be first tried with a known sample of cannabis in assaying that drug? Dogs vary much in their susceptibility and several may be tried before getting one which reacts satisfactorily.[1]

Some Things Never Change -

In view of the lack of any scientific scrutiny of the claims made for it, echinaccea is deemed unworthy of further consideration until more reliable evidence is presented in its favor.[2]

The investigated root extracts from E angustifolia and E purpurea could not be shown to prevent upper respiratory tract infections, according to an article in the November/December issue of the AMA's *Archives of Family Medicine*.[3]

The average family spends $ 150.00 a year for medical expenses as against $ 600.00 for automobile, gasoline, radios, chewing gum, candy, and tobacco.[4]

Twenty-four thousand prescriptions were studied by the St. Louis Drug Store Survey. The study showed that only one-fourth of the total number called for manufacturers' specialties alone. One half called for official products, the remaining fourth being mixed.[4]

Extracts of brain tissue have been found to possess blood pressure reducing properties.[5]

Butter is the only food product which may be artificially colored and sold without being so labeled, under the Federal Food and Drugs Act.[5]

The average price of prescriptions is about ninety-two cents.[5]

It was a druggist by the name Ballard who showed Pasteur how to grow cultures of bacteria in flasks without admitting dust but permitting the free entrance of air.[5]

The per capita wealth of the United States was $ 2,677 in 1930. For Maryland, the figure was $ 2,506 and for Delaware $ 2,706.[6]

Studies have shown that each person in this country spends about six dollars a year on medicines, making a grand total of $ 715,000,000.[6]

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5. The Maryland Pharmacist, C. Jelleff Carr, *And Did You Know That*, October 1932.
6. The Maryland Pharmacist, October 1932.

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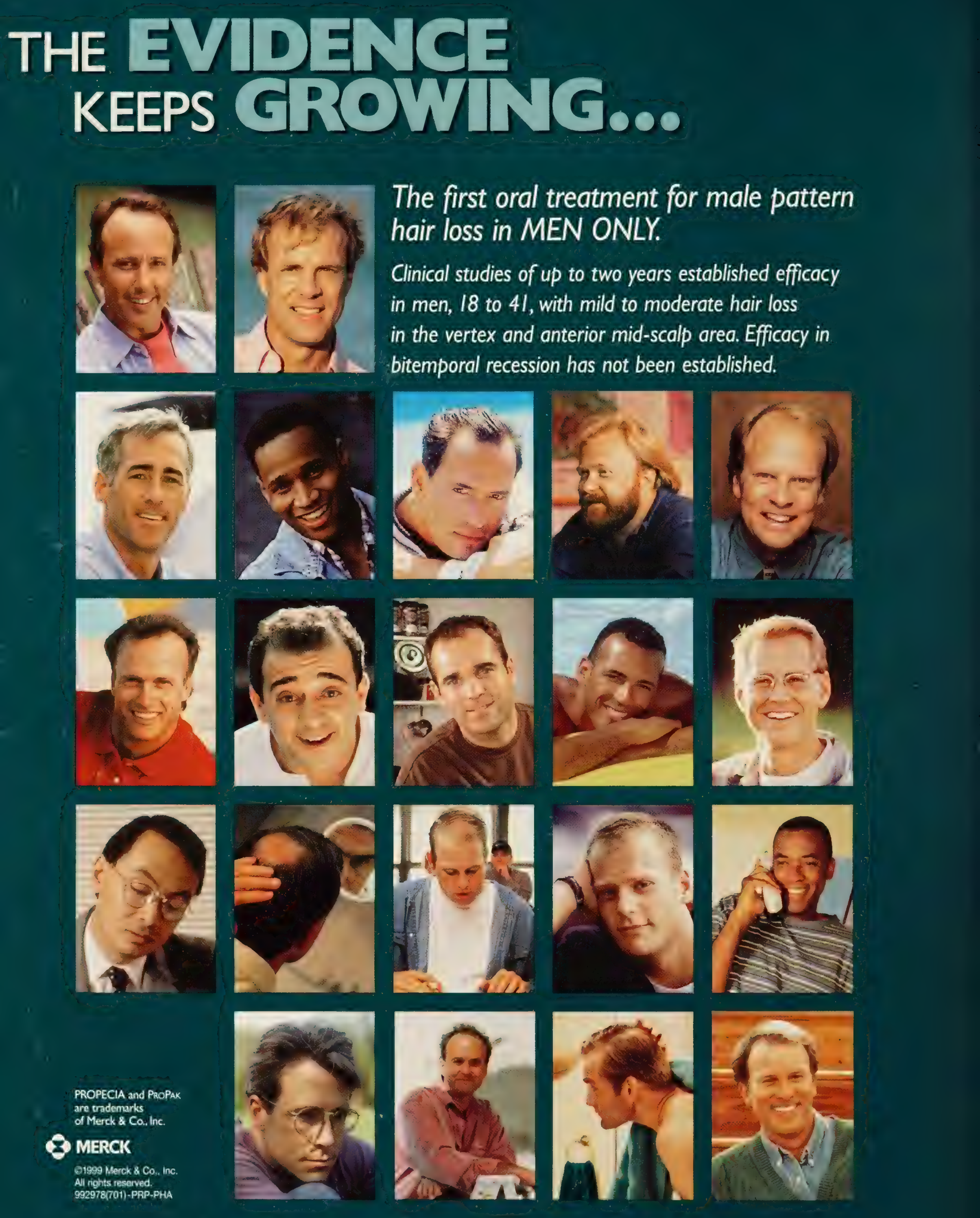

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STUDY AFTER STUDY

Maintains hair count

83% of men maintained or increased hair count at 24 months in vertex studies (v. 28% placebo). Early benefits of slowing hair loss can be seen at Month 3 based on patient self-assessment. A new 12-month study showed that PROPECIA increases hair count by increasing the number of hairs that are actively growing ($p<0.001$ v. placebo).[1]

PATIENT AFTER PATIENT

Regrows natural, visible hair

66% of men had visible hair regrowth in vertex studies (v. 7% placebo) based on global photographic assessment. In addition, investigators rated 80% of patients as improved (v. 47% placebo).

Excellent safety profile

Each drug-related adverse event occurred in <2% of men.

Adverse events at 12 months	PROPECIA 1 mg (N=945)	Placebo (N=934)
Decreased libido	1.8%	1.3%
Erectile dysfunction	1.3%	0.7%
Ejaculation disorders	1.2%	0.7%
(Primarily decreased ejaculate volume)		

Patients completed a self-administered questionnaire to detect more subtle changes in sexual function; results were consistent with the above table. No significant difference was seen in overall satisfaction with sex life.

Convenient oral, once-daily dosing

Recommend ProPak™— a convenient 3-month supply of PROPECIA that includes a cash back offer for patients.

For use in MEN ONLY

Women who are or may potentially be pregnant must not use PROPECIA nor should they handle crushed or broken PROPECIA tablets because doing so may cause abnormalities of the external genitalia of a male fetus.

If PROPECIA has not worked within 12 months, further treatment is unlikely to be of benefit.

Before dispensing PROPECIA, please read the brief summary of Prescribing Information on the following page.

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(finasteride)

Helping make hair loss history™

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1. Data available on request from Professional Services, WP1-27, Merck & Co., Inc., West Point, PA 19486. Please specify information package DA-PRP3.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINDICATIONS

PROPECIA is contraindicated in the following:

Pregnancy. Finasteride use is contraindicated in women when they are or may potentially be pregnant. Because of the ability of 5α-reductase inhibitors to inhibit the conversion of testosterone to DHT, finasteride may cause abnormalities of the external genitalia of a male fetus of a pregnant woman who receives finasteride. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the pregnant woman should be apprised of the potential hazard to the male fetus. (See also WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; and PRECAUTIONS, *Information for Patients* and *Pregnancy*.) In female rats, low doses of finasteride administered during pregnancy have produced abnormalities of the external genitalia in male offspring.

Hypersensitivity to any component of this medication.

WARNINGS

PROPECIA is not indicated for use in pediatric patients (See PRECAUTIONS, *Pediatric Use*) or women. (See also PRECAUTIONS, *Information for Patients* and *Pregnancy*.)

EXPOSURE OF WOMEN–RISK TO MALE FETUS

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; PRECAUTIONS, *Information for Patients* and *Pregnancy*.)

PRECAUTIONS

General

Caution should be used in the administration of PROPECIA in patients with liver function abnormalities, as finasteride is metabolized extensively in the liver.

Information for Patients

Women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. (See also CONTRAINDICATIONS; WARNINGS, EXPOSURE OF WOMEN–RISK TO MALE FETUS; and PRECAUTIONS, *Pregnancy*.) See also Patient Package Insert.

Drug/Laboratory Test Interactions

In clinical studies with PROPECIA in men 18-41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0.7 ng/mL at baseline to 0.5 ng/mL at Month 12. When finasteride is used in older men who have benign prostatic hyperplasia (BPH), PSA levels are decreased by approximately 50%. Until further information is gathered in men >41 years of age without BPH, consideration should be given to doubling the PSA level in men undergoing this test while taking PROPECIA.

Drug Interactions

No drug interactions of clinical importance have been identified. Finasteride does not appear to affect the cytochrome P450-linked drug metabolizing enzyme system. Compounds that have been tested in man include antipyrine, digoxin, propranolol, theophylline, and warfarin and no interactions were found.

Other concomitant therapy: Although specific interaction studies were not performed, finasteride doses of 1 mg or more were concomitantly used in clinical studies with acetaminophen, α-blockers, analgesics, angiotensin-converting enzyme (ACE) inhibitors, anticonvulsants, benzodiazepines, beta blockers, calcium-channel blockers, cardiac nitrates, diuretics, H_2 antagonists, HMG-CoA reductase inhibitors, prostaglandin synthetase inhibitors (NSAIDs), and quinolone anti-infectives without evidence of clinically significant adverse interactions.

Impairment of Fertility

In sexually mature male rabbits treated with finasteride at 80 mg/kg/day (4,344 times the estimated human exposure) for up to 12 weeks, no effect on fertility, sperm count, or ejaculate volume was seen. In sexually mature male rats treated with 80 mg/kg/day of finasteride (488 times the estimated human exposure), there were no significant effects on fertility after 6 or 12 weeks of treatment; however, when treatment was continued for up to 24 or 30 weeks, there was an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate. All these effects were reversible within 6 weeks of discontinuation of treatment. No drug-related effect on testes or on mating performance has been seen in rats or rabbits. This decrease in fertility in finasteride-treated rats is secondary to its effect on accessory sex organs (prostate and seminal vesicles) resulting in failure to form a seminal plug. The seminal plug is essential for normal fertility in rats and is not relevant in man.

Pregnancy

Teratogenic Effects: Pregnancy Category X

See CONTRAINDICATIONS.

PROPECIA is not indicated for use in women.

Administration of finasteride to pregnant rats at doses ranging from 100 μg/kg/day to 100 mg/kg/day (5-5,000 times the recommended human dose of 1 mg/day) resulted in dose-dependent development of hypospadias in 3.6 to 100% of male offspring. Pregnant rats produced male offspring with decreased prostatic and seminal vesicular weights, delayed preputial separation, and transient nipple development when given finasteride at ≥30 μg/kg/day (≥1.5 times the recommended human dose of 1 mg/day) and decreased anogenital distance when given finasteride at ≥3 μg/kg/day (one-fifth the recommended human dose of 1 mg/day). The critical period during which these effects can be induced in male rats has been defined to be days 16-17 of gestation. The changes described above are expected pharmacological effects of drugs belonging to the class of Type II 5α-reductase inhibitors and are similar to those reported in male infants with a genetic deficiency of Type II 5α-reductase. No abnormalities were observed in female offspring exposed to any dose of finasteride *in utero*.

No developmental abnormalities have been observed in first filial generation (F_1) male or female offspring resulting from mating finasteride-treated male rats (80 mg/kg/day; 488 times the human exposure) with untreated females. Administration of finasteride at 3 mg/kg/day (150 times the recommended human dose of 1 mg/day) during the late gestation and lactation period resulted in slightly decreased fertility in F_1 male offspring. No effects were seen in female offspring. No evidence of malformations has been observed in rabbit fetuses exposed to finasteride *in utero* from days 6-18 of gestation at doses up to 100 mg/kg/day (5,000 times the recommended human dose of 1 mg/day). However, effects on male genitalia would not be expected since the rabbits were not exposed during the critical period of genital system development.

The *in utero* effects of finasteride exposure during the period of embryonic and fetal development were evaluated in the rhesus monkey (gestation days 20-100), a species more predictive of human development than rats or rabbits. Intravenous administration of finasteride to pregnant monkeys at doses as high as 800 ng/day (at least 750 times the highest estimated exposure of pregnant women to finasteride from semen of men taking 1 mg/day) resulted in no abnormalities in male fetuses. In confirmation of the relevance of the rhesus model for human fetal development, oral administration of a very high dose of finasteride (2 mg/kg/day; 100 times the recommended human dose of 1 mg/day or approximately 12 million times the highest estimated exposure to finasteride from semen of men taking 1 mg/day) to pregnant monkeys resulted in external genital abnormalities in male fetuses. No other abnormalities were observed in male fetuses and no finasteride-related abnormalities were observed in female fetuses at any dose.

Nursing Mothers

PROPECIA is not indicated for use in women.

It is not known whether finasteride is excreted in human milk.

Pediatric Use

PROPECIA is not indicated for use in pediatric patients.

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Clinical Studies for PROPECIA (finasteride 1 mg) in the Treatment of Male Pattern Hair Loss

In controlled clinical trials for PROPECIA of 12-month duration, 1.4% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably, or definitely drug-related (1.6% for placebo); 1.2% of patients on PROPECIA and 0.9% of patients on placebo discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably, or definitely drug-related in ≥1% of patients treated for 12 months with PROPECIA or placebo, respectively: decreased libido (1.8%, 1.3%), erectile dysfunction (1.3%, 0.7%) and ejaculation disorder (1.2%, 0.7%; primarily decreased volume of ejaculate:[0.8%, 0.4%]). Integrated analysis of clinical adverse experiences showed that during treatment with PROPECIA, 36 (3.8%) of 945 men had reported one or more of these adverse experiences as compared to 20 (2.1%) of 934 men treated with placebo (p=0.04). Resolution occurred in all men who discontinued therapy with PROPECIA due to these side effects and in 58% of those who continued therapy.

In a study of finasteride 1 mg daily, in healthy men, a median decrease in ejaculate volume of 0.3 mL (–11%) compared with 0.2 mL (–8%) for placebo was observed after 48 weeks of treatment. Two other studies showed that finasteride at 5 times the dosage of PROPECIA (5 mg daily) produced significant median decreases of approximately 0.5 mL (–25%) compared to placebo in ejaculate volume but this was reversible after discontinuation of treatment.

In the clinical studies with PROPECIA, the incidences for breast tenderness and enlargement, and for hypersensitivity reactions in finasteride-treated patients were not different from those in patients treated with placebo.

Controlled Clinical Trials and Long-Term Open Extension Studies for PROSCAR (finasteride 5 mg) in the Treatment of Benign Prostatic Hyperplasia

In controlled clinical trials for PROSCAR of 12-month duration, 1.3% of the patients were discontinued due to adverse experiences that were considered to be possibly, probably, or definitely drug-related (0.9% for placebo); only one patient on PROSCAR (0.2%) and one patient on placebo (0.2%) discontinued therapy because of a drug-related sexual adverse experience. The following clinical adverse reactions were reported as possibly, probably or definitely drug-related in ≥1% of patients treated for 12 months with PROSCAR or placebo, respectively: erectile dysfunction (3.7%, 1.1%), decreased libido (3.3%, 1.6%) and decreased volume of ejaculate (2.8%, 0.9%). The adverse experience profiles for patients treated with finasteride 1 mg/day for 12 months and those maintained on PROSCAR for 24 to 48 months were similar to that observed in the 12-month controlled studies with PROSCAR. Sexual adverse experiences resolved with continued treatment in over 60% of patients who reported them.

Adverse Effects Reported in Post-Marketing Experience for PROSCAR (finasteride 5 mg)

Breast tenderness and enlargement, as well as hypersensitivity reactions, including lip swelling and skin rash have been reported.

DOSAGE AND ADMINISTRATION

The recommended dosage is 1 mg once a day.

PROPECIA may be administered with or without meals.

In general, daily use for three months or more is necessary before benefit is observed. Continued use is recommended to sustain benefit. Withdrawal of treatment leads to reversal of effect within 12 months.

For more detailed information, please read the complete Prescribing Information.

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Net Talk

The Wheat from the Chaff

by Bill Felkey

In case you hadn't noticed, there is a lot of garbage on the World Wide Web. One study has shown that consumers who have Web access are making inquires on health-related topics in well over 25% of their searches. Unfortunately, some of the information they are receiving is not worth the pixels through which it is displayed. Have you had a patient come into your pharmacy and ask you something like, "Does garlic really cure cancer?" A recent *Journal of Family Medicine* study showed that 53% of the 2,000 patients interviewed use alternative forms of medicine. Of those, only 37% had informed their physician that they were using an alternative treatment.

Another study specific to drug information showed that over half of the information on the Web is either incorrect or biased. You may remember the publication, sponsored by a manufacturer, called, "What Your Patients Are Reading." Its purpose was to alert pharmacists to the kinds of lay literature on healthcare topics being promulgated to the public. Being so equipped, it was hoped that pharmacists would have a ready answer when confronted with questions prompted by these unfounded claims.

Were the same publication to be printed today, it could be titled, "Where Your Patients Are Surfing." So what is a pharmacist to do? In my talks to pharmacists, I am always vigilant to point out the need to ascertain the source credibility of any Web site they use in patient care and/or medication-related decision making. The credibility issue is starting to be made easier by the creation of medicine-specific search engines such as the Medical Matrix Web site found at www.medmatrix.org. The site promotes having ranked, peer-reviewed, annotated, updated medical resources. It has an impressive listing of editorial advisors and it has divided the information it presents into numerous clinical specialties.

Over half of the information on the Web is either incorrect or biased.

Here is what they say about their efforts: "Medical Matrix is a project to improve the global medical community's access to useful digital clinical medicine documents. It is an academic iformatics effort that is attempting to contribute to a global initiative to create a 'Multimedia Medline for the 21st century'." Its editorial board is drawn from the American Medical Informatics Association's Internet Working Group.

Pharmacist As Guide

While I advocate the advantages of such a screening of the Web, the more practical problem is what a pharmacist can do, right now, to help patients. I believe we can help to filter for what patients are reading, and therefore believing and acting out. This can be done from the pharmacy's Web site (individually or cooperatively managed by software vendors) by selecting and hyperlinking your visiting patients to relevant patient information sites. You are, in essence, deciding where you want your patients to surf. You can allow them Internet access from your pharmacy. Or, you can give patients a business card or printed flier noting your pharmacy's URL so that they can visit your pharmacy's Web site from their home.

In the November/December 1998 issue of the magazine *Computer-Talk,* I talked about downloading Web sites onto your hard drive so that patients will not inadvertently link into innappropriate material. The solution of storing Web sites on your hard drive or employing a proxy server will work for a pharmacy-based workstation. The strategy for the patient visiting your site from home is to instruct patients to bookmark your pharmacy site and to use the "back" button on their browser to keep from hyperlinking into uncharted waters.

Start simple. If your practice has a strong focus on the care of patients with diabetes, post a link on your Web site to the American Diabetes Association (www.diabetes.org). You can have confidence that the information contained on this site is gold-standard quality. Interestingly, you can even link to a disease state-specific version of the information for your patients.

Patients often want more information on a condition or drug than your time allows or your computer-generated leaflet contains. Perhaps you could send them to the Healthy Lives Web site (www.healthylives.com) sponsored by Glaxo Wellcome, where they can review the extensive lay-language disease monographs from asthma to ulcers. This is, of course, another good source of credible information.

Where do you go next? I am offering members of MPhA a list of 1,800 reviewed Web sites that were validated by the Mosby Publishing Company (www.mosby.com/mosby/open) for the use of healthcare professionals. My colleague Robert Pearson develops international databases for the company and has gained permission for me to distribute the list. If you are a pharmacist interested in building a patient-oriented Web site or a software vendor that is beginning to incorporate Web resources for your pharmacy users, you may e-mail me requesting the list (felkebg@mail.auburn.edu). If you are a novice Internet user, request instructions and I will attach those as well.

With a 10% growth rate per month of new medically related Web sites on the Internet there is no shortage of information from which to choose. The issue is tapping into the "good stuff."

Bill G. Felkey, M.S., is Associate Professor of Pharmacy Care Systems at the School of Pharmacy, Auburn University. For more ideas visit his Web site: www.auburn.edu/pcs.html

MP

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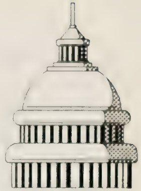
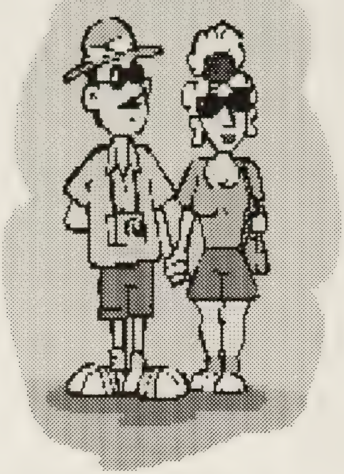
1999 Legislation Affecting Pharmacy

Bills Introduced in the Maryland General Assembly



Bill	Title	Sponsor/Committee	Description	Result w/amendments
House Bill 182 *(Senate Bill 135)*	Patients' Bill of Rights	Administration/Economic Matters	Limited access to Non Formulary Drug without restrictions on copay	Passed
House Bill 280	Reimbursement to Health Care Practitioners	Goldwater/Gordon/Economic Matters	Prevents reimbursement by carriers at less than cost of oncology drugs in office	Passed
House Bill 296	Assisted Living Programs/Small Facilities	Nathan-Pulliam, Burns, Cane, D. Davis, A. Jones, Love, Oaks, and Morhaim/Environmental Matters	Extends July 1, 2000, the date sanctions can be imposed	Passed
House Bill 674	Physician Assistants	Redmer/Environmental Matters	Requires approved job description from BPQA for prescriptive authority	Passed
House Bill 980	Insurance-Pharmaceutical Benefits	Hurson/Economic Matters	Amended to HMO-formulary development process-accreditation status	Passed
Senate Bill 135 *(House Bill 182)*	Patients' Bill of Rights	Administration/Finance	Crossfiled with HB 182	Passed
Senate Bill 586	State Board of Pharmacy	Refinements to improve clarity/Economic and Environmental Affairs	Define Rx area, define supervision (on-site), Reciprocity with CA and FL, Renewal dates	Passed Senate; killed in Environmental Matters in House
Senate Bill 319	Assisted Suicide Prohibition	Stone/Judicial Proceedings	Cannot knowingly aid suicide; pain meds exempted w/o knowledge	Passed
House Joint Resolution 16	Task Force on Medical Records	Taylor, Goldwater/Environmental Matters	One rep from "pharmaceutical manufacturer" without PBM	Failed



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Registration Brochure Page 9

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Increased Risk of Morbidity and Mortality in Older Adults After the Death of a Spouse

Community Resources Available for Bereaved Elderly in Maryland

Catherine Cho
Pharm.D Student III
University of Maryland School of Pharmacy

Among the most traumatic life events that occur to individuals, death of a spouse can be one of the most devastating. While it is expected that a bereaved spouse will suffer emotional pain and will endure a period of grief and mourning as he or she copes with this major life change, an increased incidence of morbidity or even mortality is not expected. This correlation between being widowed and negative health outcomes is called the "bereavement phenomenon."[1] Older adults experiencing the loss of a spouse may be even more predisposed to negative outcomes, given the prevalence of chronic disease in this population.

Relationship Between Spousal Bereavement and Increased Morbidity and Mortality

A number of studies have investigated the bereavement phenomenon. Kaprio et al.[2] observed 7,635 deaths in a widowed population of 95,647. After comparing the actual prevalence for each cause of death to expected prevalence rates, they found a significantly higher overall mortality rate from natural causes, violent causes (automobile accidents, suicides) and cardiovascular diseases among the widowed population. A trend noted increased deaths at one week and at six months post-bereavement. Elderly men were at increased risk in the first six months, and older women within the first month.

A similar study by Helsing et al.[3] confirmed these findings. In this case controlled study, 4,032 widowed persons were matched to 4,032 married controls. Male survivors had significantly higher mortality rates for infectious diseases and suicides compared to married men. Female survivors had significantly increased mortality due to hepatic cirrhosis. For all other causes of death, there was a trend that did not reach significance for increased mortality among the bereaved group. Thompson et al.[4] compared 212 widowed individuals to 162 married controls using self-reported measures of morbidity. The widowed group reported more episodes of new or worsened illness, greater severity of illness, and greater increases in medication use at two months post-bereavement. At one year there was an increased mortality rate for bereaved men.

In a somewhat different study design, Murrell et al.[5] observed the effect of a number of losses among 1,084 persons over 55 years of age. These included "attachment" bereavement (loss of a spouse, parent, or child), "non-attachment" bereavement (loss of a sibling, grandchild, friends) or other losses (e.g., pet, house, job, finances, divorce). Compared to a matched control group, there were no significant increases in mortality rates, medical events including new illnesses or injuries, or use of medical services or medications. One limitation of this study is that the number of subjects experiencing spousal bereavement was very small.

Three hypotheses have been suggested to explain the bereavement phenomenon: (1) homogamy, (2) a joint unfavorable environment, and (3) the psychosomatic hypothesis.[2,5,6] The homogamy hypothesis suggests that the unfit tend to marry partners who are similarly unfit, therefore being at increased risk of mortality.[6] Studies have found a significant correlation in deaths of spouses caused by infectious diseases, arteriosclerotic and degenerative heart disease, cancer, and others, however, the concordance among deaths from infectious diseases was only significant before the advent of highly effective antibiotics.[3] The concept of a jointly shared unfavorable environment or unavailability of medical services could be a factor contributing to negative health outcomes, however, when this hypothesis was tested by Murrell et al.[5], physical and socioeconomic environmental factors such as education, housing quality, health and available social services, did not predict morbidity or mortality after attachment losses. The most generally accepted explanation for the bereavement phenomenon is based on the psychosomatic hypothesis which proposes that psychosocial stress affects health.[6] "Traumatic grief" or "complicated grief" describes a state different from depression and anxiety which accompanies conjugal bereavement.[7,8] Symptoms such as intrusive thoughts of the deceased, yearning and searching for the deceased, lack of acceptance of the death, shock avoidance of reminders of the deceased, feelings of bitterness, survivor's guilt, and symptoms of identification (e.g, feeling pain in the same body parts as the deceased) are associated with traumatic grief.

The Inventory of Complicated Grief (ICG) was developed to assess traumatic grief.[7,8] Prigerson et al.[7] found that spouses with a high score at six months post-bereavement had an increased incidence of cancer, cardiovascular disease, anxiety, influenza and suicide ideation. A similar study by Szanto et al. confirmed these findings.[8] Altered immune function post-bereavement may contribute to this increase in morbidity and mortality.[9]

Interventions

While there is little that can be done to take away the pain experienced upon loss of a spouse, those who are having difficulty adapting to that loss should be identified and referred for assistance to reduce the risk of negative outcomes in these individuals. Patterson[10] found that participation in leisure activities may reduce stress during the recovery period post-bereavement. Participation in support groups, specifically the formation of new friendships and bonds, was also found to be helpful.[11]

In Maryland, all senior centers have information and referral services to assist older adults who wish to find a support group or other resources to deal with bereavement. In addition to senior centers, support groups may be held at local hospitals, churches or other community centers. Pharmacists who care for older adults can learn more about the services in their communities by contacting Senior Information and Assistance at the Maryland Department of Aging at 1-800-AGE DIAL.

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Continuing Education for Pharmacists

Volume XVI, No. 12

Patient Counseling: Irritable Bowel Syndrome

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Goals. The goals of this lesson are to discuss the irritable bowel syndrome, and provide information to assist pharmacists in counseling patients with the disorder.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the irritable bowel syndrome and identify its potential causes;
2. recognize the non-pharmacologic means to treat and/or prevent symptoms of the irritable bowel syndrome;
3. identify therapeutic agents used to treat the affliction, including pharmacologic, toxicologic, and pharmacokinetic considerations when appropriate; and,
4. demonstrate an ability to counsel patients on prevention and treatment of the irritable bowel syndrome.

Provided As a Service to the
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Irritable bowel syndrome (IBS) is the most common patient complaint of persons who visit gastroenterologists. Approximately one in six adults in the U.S. is afflicted, with fewer than 20 percent of them consulting a physician. Although not life threatening, IBS can cause intense distress to its sufferers and frustrate physicians.

This lesson will assist pharmacists in counseling patients with IBS. It discusses causes, describes treatment with OTC and prescription products, and differentiates IBS from more serious organic pathologies. It also provides specific information for pharmacists to use when counseling patients to maximize the probability of successful treatment.

The Irritable Bowel Syndrome

IBS is a functional disorder without accompanying structural changes characterized by irregular flare-ups and remissions of one or more of the symptoms listed in Table 1. It is a poorly understood disorder, with an obscure etiology and prognosis.

Table 1
Symptoms of Irritable Bowel Syndrome

Major Symptoms
abdominal pain
constipation
diarrhea
Associated Symptoms
abdominal distension or flatulence
frequent loose stools with onset of pain
pain eased by defecation
sensation of incomplete evacuation
excessive rectal mucus production
Other Symptoms
Upper Gastrointestinal
heartburn
early satiety
excessive belching
dyspepsia
vomiting
nausea
Non-intestinal
urinary frequency
dysmenorrhea
fatigue
dysuria
nocturia
headache

IBS has been referred to by a variety of names including nervous indigestion, nervous diarrhea, irritable colon, spastic colitis, functional dyspepsia, intestinal neurosis and pyelospasm. Laxative or cathartic colitis also describe the condition when caused by overuse of these substances. These descriptors may be appropriate when referring to individual symptoms; however, they are less acceptable when describing the basic problem. The terms have been replaced largely by the more inclusive one: *irritable bowel syndrome.*

There have been numerous attempts to describe IBS in terms of what it is not. For example, it is not an organic disease. Its sufferers do not have anatomic or biochemical abnormalities of the GI tract.

The primary symptoms of IBS include one or more disturbances in intestinal motility. Classic symptoms include abdominal pain or distention, and constipation that may alternate with diarrhea. Pain or distention is relieved by moving the bowels and this feature is part of the diagnosis protocol. There is no standard definition or specific pathophysiologic diagnostic sign of IBS. Most experts define the condition by eliminating other considerations as noted above.

The etiology of IBS is idiopathic (unknown or unexpected) for some persons. Its pathology may differ for each person.

Symptoms usually onset in young adulthood. Women are affected more than twice as frequently than men. IBS rarely appears for the first time after age 50, with one-half of patients experiencing onset of symptoms before they reach the age of 30. Whenever symptoms onset later in life, this normally signals the presence of organic bowel disease. IBS is also recurrent and chronic. Symptoms may persist at least three months.

Possible Causes of IBS

Food. A large number of foods have been identified as possible aggravators of IBS. Two-thirds of affected patients in one study were intolerant to one or more of the following items: dairy products, corn, wheat, coffee, tea, and citrus fruit. There was no evidence of an immunologic cause for their intolerance.

The concentration of prostaglandin E_2 increases in the rectal tissues of persons who experienced diarrhea after ingesting the offending food. It is therefore tempting to speculate that an enhanced production of prostaglandin E_2 may be a causative factor. Countering this argument is that diarrhea is not a predominant symptom in most IBS sufferers. Prostaglandins may play a role, but the involvement is most likely limited to the diarrheal phase of IBS, or to a subgroup of patients.

Dietary fat, chocolate, onions, potatoes, alcohol, salads, raw fruits and vegetables, and tomatoes have also been listed as instigators of increased intestinal motility and abdominal pain. Foods that are high in fiber but ingested without the requisite amount of water to permit the fiber to swell and increase in bulk, are poorly tolerated generally. On the other hand, adequate fiber and fluids are useful in treating the condition as shall be seen shortly.

Low-residue Diet. The benefits from the stool-bulking action of fiber had been hypothesized since the time of Hippocrates. However, it wasn't until the early 1970s that the benefits were truly realized.

In a study of population groups living in Africa, it was demonstrated that there is a positive correlation between the slow moving, low-residue (small, hard) stools characteristic of Western societies and low-fiber diets. It was eventually shown that high-fiber diets can prevent IBS. Since those pivotal observations, further investigation has corroborated the conclusions: if dietary fiber deficiency is not the actual cause of IBS, it is at least a major contributor in many cases.

Drugs. Numerous drugs are reported to modify gastrointestinal function and trigger IBS symptoms. In one investigation of 27 patients with unexplained diarrhea, the surreptitious use of laxatives or diuretics was the instigator of unexplained diarrhea in seven and two patients, respectively.

Stress. Stress is implicated as a cause. IBS patients are often described as being more neurotic, anxious, or depressed than persons who do not suffer from the disorder. Individuals with IBS often report a history of nervousness, emotional disturbance, hysteria or depression. Infection, the common cold, acute illness, even a change in the weather, and all causes of stress may worsen IBS symptoms.

A good history should be taken on likely IBS candidates because actual cases end up being few in number. As stated, most patients with functional gastrointestinal complaints never visit a physician and, therefore, cannot be characterized as having predisposing conditions.

Dysentery. Twenty-five percent of individuals with IBS in one study dated their onset of symptoms to a bout of gastroenteritis. Intestinal infection, therefore, may play an etiologic role.

Table 1 lists a symptom profile of an IBS patient. The individual is often a heavy user of laxatives and is very bowel conscious. Either constipation or diarrhea usually predominate, or they appear alternatively, oftentimes in a predictable cycle.

Distinguishing IBS from Organic Bowel Disease

IBS must be differentiated from more serious organic diseases such as cancer (Table 2) before initiating treatment. Once a physician diagnoses IBS and supervises the patient's self-therapy, initial treatment of symptoms will most likely consist of OTC medications.

Unlike IBS, organic disease may be characterized by anemia, severe weight loss, bloody stools, and frequently, fever. A history of awakening from sound sleep with nocturnal diarrhea suggests organic bowel disease.

In a well-nourished patient, chronic symptoms and lack of personal and family histories of organic disease are important to diagnosing IBS correctly. IBS sufferers also may experience abdominal pain that is relieved by defecation as mentioned earlier; loose, frequent stools; abdominal distension; mucous stools; and a sensation of incomplete evacuation after defecation.

IBS should be suspected whenever there are multiple symptoms, or when the cause is otherwise unexplained or recurrent. When suspected, the individual with IBS should be directed to a physician. Once the condition has been diagnosed and other pathologies ruled out, IBS can often be managed appropriately with OTC drug

Table 2
Conditions That May Mimic Irritable Bowel Syndrome

- colorectal neoplasia
- inflammatory bowel disease
- diverticular disease
- giardiasis
- celiac disease
- lactose intolerance
- excessive ingestion of incompletely absorbed carbohydrates

products, along with physician counseling.

Treatment

When the symptoms listed in Table 1 appear alone or occur infrequently, they may often be managed effectively with self-therapy. The goal of drug therapy is not to cure IBS, but to treat specific symptoms.

Effective treatment must be individualized. Along with recommendations for OTC products, patients may also receive prescriptions for adjunctive therapy including psychotropics, sedatives, anticholinergics, antiperistaltics, dopamine antagonists, H-2-antagonists and calcium channel blockers. Antidiarrheals or laxatives may be prescribed for short periods, when appropriate. The decision to prescribe drugs must be considered carefully. They may be required for long periods, thus increasing the chance for adverse effects, and adding to the expense of treatment. Permanent and complete cures are rare.

Fiber. Maintaining an adequate dietary fiber intake helps correct many dysfunctions of the colon. The best documented action of dietary fiber is to increase the softness and bulk of the fecal mass due to fiber's affinity to absorb water and swell, thus increasing the fecal bulk. Alternative mechanisms include fermentation of fiber's carbohydrate content and increasing the concentration of fecal bacteria.

Fiber is a mainstay in the treatment of IBS. It normalizes the fecal transit time, meaning that it decreases it when too rapid, and increases it when too slow. Fiber can reduce the intraluminal pressure, particularly in the sigmoid colon, and enhance flatus production.

Soluble fiber (e.g., psyllium, oat bran) is more effective for treatment of IBS than insoluble fiber (e.g., cellulose, wheat bran). Wheat bran should be reserved for patients who do not respond to other forms of fiber since it may exacerbate symptoms of diarrhea in some patients.

Fiber is safe when ingested in large quantity in the diet or as an OTC high-fiber supplement product. In either form, it is acceptable for long-term therapy. Many physicians recommend high-fiber dietary supplementation for treating patients with IBS, especially those whose dominant symptoms are constipation and hardened stools.

OTC fiber products are acceptable for long-term use. In fact, patient compliance may be greater with these products than with high-fiber diets. Doses must be individualized. It will probably require several weeks to a month of continuous therapy to notice significant improvement.

In an investigation of 26 patients with IBS, the effect of high-fiber versus low-fiber diets was compared to the onset and control of symptoms. Individuals who ingested a fiber supplement equivalent to six to seven grams of dietary fiber per day showed significant improvement in subjective symptoms, and objective changes in colonic motor function within six weeks. Individuals in the low-fiber intake group showed no such improvement.

Simethicone. Simethicone is an inert silicon polymer that consists of a mixture of dimethylpolysiloxane with approximately 5 percent silica gel. Excessive flatulence can be managed safely and effectively with simethicone. It is the only FDA-approved OTC antiflatulent and is the basis for antacid/anti-gas products.

By lowering the surface tension of gas bubbles, simethicone coalesces them into larger ones. In this form, they can be eliminated more readily by belching or passing flatus.

Simethicone is not absorbed from the intestine, so there are no systemic adverse effects associated with its use.

Enzyme Replacement. *Lactase* deficiency should be suspected as a cause of IBS. Sufferers who associate onset of symptoms with consumption of dairy products including milk, ice cream and cheese may have a lactase deficiency.

Dairy products require lactase, which is normally present in the intestinal mucosa for digestion. In lactase-deficient individuals, lactose is not properly digested or absorbed. Once it reaches the colon, bacteria ferment it. Two grams of lactose may produce up to 1,400 mL of gas.

Individuals with lactase deficiency should try to avoid dairy products. If this is not possible, they may benefit from OTC products (e.g., Lactaid, Dairy Ease) which replace the deficient enzyme. Some products may be swallowed or chewed. Others may be added to milk or sprinkled onto dairy products before consumption.

Other products (i.e., Beano) contain *galactosidase,* an enzyme that prevents gas formation from many high fiber foods including beans and cabbage. The enzyme breaks down complex carbohydrates to increase their digestibility, making them less likely to cause intestinal gas and bloating.

Counseling Patients on Irritable Bowel Syndrome

Persons with IBS can be helped in two major ways: by providing drug therapy, and counseling patients so they can understand and cope with their condition. A primary goal is to help them avoid the events that predispose to symptoms and/or aggravate their intensity.

Before advising a patient with IBS, the total drug history of both OTC and prescription medications should be evaluated. Aggravating

Table 3
Patient Advice for Irritable Bowel Syndrome

Patients should be aware that:

- Irritable bowel syndrome is not an ulcer or cancer, does not lead to either condition, and is not life-threatening. Symptoms occur because the intestinal tract is not functioning properly. With corrective treatment, sufferers can lead a normal, active and healthy life.
- They should follow their doctor's advice carefully on pursuing tension-relieving activities including sports, hobbies and physical exercise. A positive self-image and extroverted personality will help control symptoms.
- They should avoid chewing gum, drinking carbonated beverages, and ingesting other food and confectionery items that increase the swallowing of air. Caffeine- or alcohol-containing beverages, and tobacco products can seriously aggravate the condition, and should be avoided.
- A hot-water bottle or moist heat source placed on the abdomen may help relieve severe spasm and cramping.
- They should eat at the same times every day, chew food slowly and thoroughly, and drink eight to 10 glassfuls of fluids each day.
- They should avoid foods that are known to cause discomfort. A doctor or pharmacist can help them plan a healthy diet.
- Breath mints and other confections that contain sorbitol or mannitol may cause excessive flatus or diarrhea, and worsen symptoms. They should be used sparingly, if at all.
- They should tell their doctor and pharmacist about all the drugs they take, including both prescription and OTC items. The same is true for natural products and dietary supplements.
- Although the condition may be controlled satisfactorily with OTC products, it is important that IBS sufferers visit their doctor regularly.
- They should not delay the urge to have a bowel movement, avoid straining, and try to relax during bowel movements.
- They should not use stimulant laxatives.

Concerning OTC fiber-supplement products, patients should:

- Carefully follow the directions on the label of all products. Any patient who has a question about the correct use of a product should talk to a doctor or pharmacist.
- If there is GI tract discomfort when the product is first started, decrease its dose to about one-fourth of what is recommended, then slowly increase it over the next several days, unless a doctor has directed otherwise.
- Take the product with a full glass (eight ounces) of water or fruit juice, and drink at least eight to 10 glassfuls of liquid each day.
- Experiment with different powder, granule or wafer forms of OTC fiber supplements to avoid taste fatigue. Powder or granule products may taste better if mixed in cold, even iced, beverages. Mixing in a blender may improve the taste even more.

drugs can include OTC products such as antacids and laxatives. The patient's use of natural products should be checked as well. Probing should be intense since patients may attempt to conceal their use of OTC drugs and natural products from physicians and pharmacists.

Patients should eat at the same times each day with attention to the ideal diet for them. They should receive adequate sleep and comply with instructions for recreation and exercise. Physical activity can improve intestinal motility and reduce anxiety. Tobacco and alcohol should be avoided since they can stimulate intestinal motility and increase gastric acid production.

Foods that intensify symptoms should be avoided. Maintaining a diet diary for one month may help identify aggravating items. Once a food is suspected to be an offender, it can be eliminated from the individual's diet for awhile, then reintroduced. If symptoms return when the offending food is then ingested, that food can be considered a predisposing cause of symptoms.

Patients initiating therapy with fiber supplements should be counseled that increased gaseousness and bloating may occur early in therapy. This is because the intestinal flora have been presented a relatively large amount of carbohydrate to digest, which increases intestinal content of carbon dioxide as a byproduct of bacterial fermentation. Most individuals will adjust to this over the next week or two. If it is bothersome, doses may be reduced to about one-fourth of the recommended intake, and then increased slowly every four to seven days until the desired therapeutic effect is obtained.

Patients may fear they have cancer or other serious disease due to the long-term nature or severity of the symptoms. IBS is not cancer or a serious organic disease.

They should also be reminded that while IBS cannot be self-diagnosed, it can often be treated with OTC products after a physician has diagnosed it. When these products are used, their directions must be followed carefully.

Information in Table 3 may be helpful in counseling patients with IBS.

Pharm/alert® Notes

Counseling Notes for Pharmacists

Too Much Sun = Cancer, Cataracts & Wrinkles

The absence of sunlight in winter may cause seasonal depression, but too much sun in the summer can cause skin cancer, premature aging, and cataracts.

Today most people know that exposure to the sun causes skin cancer. Of all cancers, it is the most prevalent, with more than a million new cases diagnosed annually. The most common types of skin cancer are *basal cell carcinoma, squamous cell carcinoma and malignant melanoma.*

Basal cell carcinoma usually appears as raised, translucent lumps or bumps. While it does not often spread to other parts of the body through the blood stream, basal cell carcinoma can cause local damage and disfiguration through direct growth and invasion. Squamous cell carcinoma is usually distinguished by raised reddish growths, which can spread to other parts of the body. About 2,000 deaths occur annually from this form of cancer. Malignant melanoma, the most serious type of skin cancer, appears first as a light brown to black irregularly shaped blemish. It spreads to other parts of the body through the bloodstream and lymph system. If undetected and untreated, melanoma kills—7,000 people in the U.S. die each year from malignant melanoma.

Premature aging and wrinkling of the skin is another deleterious effect of excessive exposure to the sun. People who stay out in the sun too much begin to show signs of photoaging before the age of 30, while skin that ages chronologically doesn't show such changes until 40+ years of age. Manifestations of aging skin include fine wrinkles, freckles, dilated capillaries, irregular pigmentation (liver spots), and a general loss of elasticity.

Cataracts and other eye disorders are also caused by exposure to the sun and UV rays. Cataracts are a leading cause of blindness—and 50% of adults over the age of 60 are estimated to have them. Other eye problems associated with UV exposure include corneal sunburn and growths on the outer surface of the eye.

Few people are aware of the association of cataracts and other eye problems with sun exposure, so be sure to tell your patients about this potential hazard.

Both skin and eye damage from the sun can be prevented or minimized. Advise people to avoid long exposure to direct, or even diffuse, sunlight—particularly at peak times (10 a.m. to 3 p.m.). Other preventive measures include:

- Apply sunscreen with SPF≥15 to all exposed areas of the body.
- Re-apply sunscreens every two hours, even on cloudy days.
- Wear clothing that covers the entire body.
- Wear a broad-brimmed hat to shade both face and eyes.
- Wear sunglasses when outdoors, even when it's overcast!

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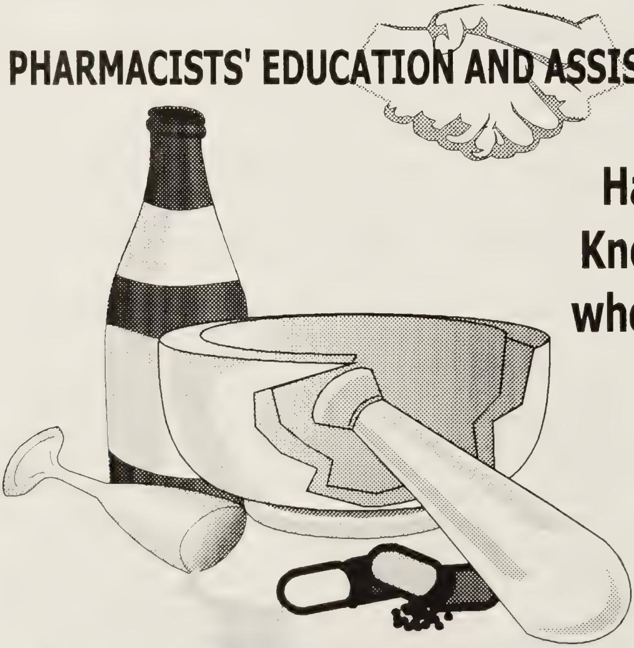

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Drug-Food Interactions

The use of computerized drug interaction screens, built into community pharmacy computer systems and used by many on-line, point-of-sale prescription claim adjudication systems, have become an important tool for pharmacists in preventing negative outcomes associated with drug-drug interactions. Food-drug interactions are more challenging (since food consumption is not documented on patient profiles), but often pose equally substantial risk of negative outcome. Consider this brief case-in-point adapted from the records of the University of Wisconsin Hospital and Clinics (this describes an actual case, but many details have been modified).

Case: A forty-nine year old male patient with a history of severe depression is placed on a monoamine oxidase inhibitor (MAOI) after failing on treatment with tricyclic antidepressants and selective serotonin re-uptake inhibitors. The patient was warned of possibly severe hypertensive reactions associated with the consumption of foods high in tyramine (a pressor amine) while on the MAOI. The patient remained adherent to a tyramine-free diet for several months, and was showing dramatic response to the new therapy. As the patient's depression diminished, his appetite returned, and on one occasion he consumed a substantial quantity of chocolate (known to contain some tyramine, but generally considered safe for consumption in moderation in tyramine-free diet). Two hours later, the patient presented to the Emergency Department complaining of a severe headache. A diagnosis of hypertensive crisis was made and treatment with nitroprusside was begun. Unfortunately, the patient suffered a stroke and died within 20 minutes of treatment initiation.

Despite the appropriate education and warnings provided by the patient's physician and pharmacist, this food-drug interaction caused the death of a patient. It is critical that pharmacists remain aware of potential food-drug interactions, recognize that they will not be warned of potential interactions by their standard drug-drug interaction software, and intervene with information and education when necessary. — Lee Vermeulen

Summary:

Interactions between foods and drugs can have profound influence on the success of drug treatment and on the side effect profiles of many drugs. The interactions are not always detrimental to therapy, but can in some cases be used to improve drug absorption or to minimize adverse effects. These interactions have received more attention recently, especially drug interaction with grapefruit juice. As new drug approvals occur with ever-increasing speed, there is less information available about their adverse effects and interactions when the drugs reach the market.

A second area of concern is the use of herbal medicines and dietary supplements. These products are not rigorously monitored, and may contain little if any of the substance indicated on the label. Some of the herbs used can interact adversely with prescription drugs. Two notable examples are ma huang (ephedra) and feverfew. Ma huang is a stimulant that can cause hypertensive crises in patients taking monoamine oxidase inhibitors. Feverfew has anticoagulant properties that can augment the effects of warfarin.

Most food-drug interactions occur through three mechanisms: reduced rate or extent of absorption, increased rate or extent of absorption, or through chemical/ pharmacologic effects.

With some drugs, the presence of increased amounts of stomach acid results in the destruction of acid-labile drugs, such as penicillin G, ampicillin and dicloxacillin. In other cases, the components of food, such as calcium or iron, may form complexes with the drug that are less easily absorbed. Examples include tetracycline, sodium fluoride and ciprofloxacin. The absorption of alendronate is impaired by food, calcium and almost everything, including orange juice and coffee. It should be taken with plain water and nothing else should be consumed for at least 30 minutes. In many cases, the actual mechanism by which food interferes with absorption is not known. Delayed absorption does not necessarily reduce the total overall exposure to the drug; the area under the curve (AUC) may be equivalent regardless of how the drug is taken. A reduced rate of absorption may sometimes be useful in reducing the side effects of a drug, as in the case of ibuprofen, without reducing bioavailability.

The bioavailability of some drugs may be enhanced by food. For example, an acid environment is necessary for the absorption of ketoconazole. The absorption of griseofulvin is increased by fat in a meal. Fenofibrate, mebendazole, isotretinoin, tamsulosin, carbamazepine and labetalol are examples of drugs that will be better absorbed when taken with food. Improved absorption of a drug may or may not have a significant effect on the drug's efficacy.

Chemical or pharmacologic interactions occur through a wide variety of mechanisms. A very common interaction is that between beverage alcohol and drugs that have sedative effects. The effects of sedative drugs will usually be potentiated by the consumption of alcohol. Opiates, benzodiazepines and antihistamines are well-known examples of this phenomenon. Another alcohol-related interaction is the competitive inhibition of the enzyme aldehyde dehydrogenase, often called the "Antabuse ®" reaction. Nausea, vomiting, flushing, dizziness and tachycardia may occur with exposure to alcohol in patients taking some cephalosporins, ketoconazole, metronidazole, and sulfonylureas. In addition, chronic alcohol overuse can increase the toxicity of some drugs, as with acetaminophen and methotrexate, or reduce the drug's efficacy, as with phenytoin.

Components of food may antagonize the desired effect of the drug, as in the case of warfarin. Foods which are high in vitamin K, or which enhance vitamin K production by intestinal microorganisms, can reduce the effectiveness of warfarin in diminishing the body's supply of vitamin K, which is needed to activate clotting factors. Changing to a diet with increased consumption of leafy and/or dark green vegetables, such as spinach and turnip greens, could lessen the degree of anticoagulation made possible by warfarin by supplying additional vitamin K.

Perhaps the most feared food-drug interaction is that between monoamine oxidase inhibitors (MAOIs) and the amino acid tyramine, which is found in a variety of aged, fermented, overripe or pickled foods and beverages and, to a lesser extent, chocolate and yeast-containing foods. Tyramine is indirectly sympathomimetic. When its metabolism is suppressed, as it is by MAOIs, it can cause a significant release of norepinephrine, resulting in markedly increased blood pressure, cardiac arrhythmias, hyperthermia and cerebral hemorrhage.

The interaction between grapefruit juice and a variety of drugs has been widely reported. It appears that one or more flavonoids found in grapefruit juice inhibit some of the enzymes in the cytochrome P450 system. This results in reduced metabolism of drugs that are cleared by the same system; bioavailability may increase by as much as 200%. Patients should avoid drinking grapefruit juice for two hours before and four hours after taking drugs in this category. If the drug is in an extended-release dosage form, patients should wait until six hours have passed before drinking grapefruit juice.

A thorough list of common drug-food interactions was included in the original publication of this article. If you would like a copy of this reference, please send a self-addressed stamped envelope to:

Maryland Pharmacists Association
Attn: Drug-food Interactions
650 W. Lombard St.
Baltimore, MD 21201

Additional information about drug-food interactions can be found in these references:

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Rx AND THE LAW

By Kenneth R. Baker, B.S.Pharm., J.D.

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HOW DO WE PROTECT THE PATIENT FROM THE UNFORESEEABLE?

Occasionally when developing risk management techniques that will protect us from liability, we forget the ultimate goal of risk management is to protect those who rely on us as professionals. In the 1994 Tennessee Supreme Court case of Pittman v. Upjohn[1] neither the physician nor the pharmacy were found legally liable for the death of the adult grandson of the patient. The Court ruled it was not legally foreseeable to the pharmacy or the physician that the adult grandson would accidentally take his grandmother's Micronase®. However the young man sustained permanent brain damage requiring constant care. Regardless of legal liability, could the physician or the pharmacist have taken steps that would have prevented this tragedy?

In 1988 Bessie Richards was diagnosed as having adult-onset diabetes and received a prescription for Micronase. The directions on the prescription label were "Take one tablet daily before breakfast." Neither the physician nor the pharmacist gave any written information about the drug, nor did either counsel Bessie. At Bessie's request the prescription was filled in a non-safety cap bottle.

Six months later, Mrs. Richard's grandson, Don Pittman, 26 years old, was visiting her house. Don complained to his grandmother that he thought he had the flu and hurt all over. Bessie told Don there were some aspirin on top of the refrigerator. Don apparently took some of the Micronase. Over the next two days Mr. Pittman got worse and eventually went into a hypoglycemic coma. It was discovered he had taken six of the Micronase over the two day period.

Pharmacists, like most people who choose a career in one of the health professions, are caring people. An incident such as this has a devastating effect on the pharmacist as well as the family of the injured party. What steps could you take in your pharmacy to protect against this type of case?

As pharmacists we deal with potentially dangerous drugs which can injure as well as cure. We can not protect our patients against all bad outcomes. We can not take responsibility for everything bad that happens. There are no steps we can take to guarantee an event like in Pittman v. Upjohn never happens. We can, however, take steps to protect our patients.

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[1] 890 S.W.2d 425, (1994)

While all patients should be counseled, at least with new prescriptions, certain drugs require more information and more time. Patients need to know what they are taking and why. The Indian Health Service recommends an initial question during counseling of "What did your doctor tell you this is for?"

With all diabetic drugs the risk of hypoglycemia is potentially dangerous. Counseling about interactions, including foods, and side effects is important. Upjohn literature states:

> **Information for the Patients:** Patients should be informed of the potential risks and advantages of Micronase and of alternative modes of therapy. They also should be informed about the importance of adherence to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure also should be explained.

The physician may have already explained these things. In order for the pharmacists to make the best use of his or her time, the Indian Health Service recommends a second question to test what the patient already knows. In this case, asking the patient "What side effects and precautions did the doctor go over with you on this medication?" will discover what areas the pharmacist does not need to spend time on.

In addition, the pharmacist might strongly suggest to all patients that medication be kept in a safe place away from other medications other members of the family might take. In the Pittman case the grandson was an adult, but there are many sad cases where the child is under five years. Perhaps, even when a patient routinely requests non-safety caps, we may want to suggest that if any young children ever visit they may want to reconsider that decision. A few moments of inconvenience each day may save a child. One Kansas pharmacist who had that experience, now makes that suggestion to every patient.

The Court in the Pittman case left no doubt that had the facts been different the pharmacy would have been liable. The Court said "the pharmacy, as well as the physician owed [the patient] the duty to warn" of the "symptoms and dangers of complications that might arise from the use of Micronase."

©Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Company.

This article discusses general principals of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorney and insurance company for specific advice. The Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

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Wanted

If you are participating in or initiating a form of patient oriented practice such as the one on page 19, MPhA would like to hear from you.

We are looking for reports from pharmacists involved in pharmacy care.

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Want to Place an Ad?

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in the *Maryland Pharmacist* and reach more than 1,000 pharmacists for free. All ad copy is subject to approval and space availability. Reservations are due the first of the month preceding issue month. To place an ad, send your typewritten copy to MPhA, 650 W. Lombard Street, Baltimore, MD 21201-1572 or FAX to 410-727-2253. ♡

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50 years ago...

Permanents

The druggist has a right to the permanent wave business

For the past four years, druggists have found a wealth of new profits in home permanent wave kits. The transfer of permanent waving from beauty shops to the homes has taken sales from the beauticians and given them to the druggists and the beauticians don't like it!

In more than 20 states, the beauticians have introduced legislation in the current sessions attempting to restrict home permanent waving by one device or another. Now the question is: Has the druggist a right to this lucrative new business? We believe he has! He was granted that right by over 50 percent of the women of America. These women, given a free and unhampered choice, have preferred the economy, the convenience and the natural-look of the home wave to the professional coiffure of the beauty shop.

Yes, the druggist has a right to the permanent wave business. And yet that right is now being challenged by powerful beauty shop lobbies in more than 20 states. Not only will American women lose millions of dollars in savings that they have realized since home permanents were first introduced, but druggists in 20 states stand to lose the fastest-selling item in their cosmetic department.

Bear in mind, there is no question of the safety of home permanents. Over 50 million users of Toni and other home permanents can testify to that. Furthermore, the American Medical Association, the U.S. Food and Drug Administration and the research laboratories of Good Housekeeping, Parents' and other leading magazines can all prove that home permanent waving solutions are no more harmful than the hundreds of other cosmetics the druggist carries in his store. But no one questions these other cosmetics. Only the home permanent for the obvious reason that the permanent wave is the heart of the beauty shop business and that heart has been severely strained by the influx of home permanents.

Both beauty shops and druggists have a right to the permanent wave business, and they should fight for that right out in the open without legislative restrictions obviously aimed to hurt one group in favor of the other. It is your business (and a very important business) to know if the beauticians in your state are attempting to legislate against home waving. If they are, write your legislator, and get your state pharmacutical association to fight against every attempt to outlaw, tax or hamstring home waving.

Reprinted with permission from the Missouri Pharmacist.
(Editor's note: There was not a byline on this article, printed in the March 1949 issue of the Missouri Pharmacist.)

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Irritable Bowel Syndrome." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 12/15/01. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-98-012-H01.

Name______________________________

Address____________________________

City, State, Zip_______________________

The Maryland Pharmacy Continuing Education Coordinating Council and the Ohio Pharmacists Foundation are both approved providers of continuing pharmaceutical education for pharmacists by the American Council on Pharmaceutical Education.

1. All of the following statements about irritable bowel syndrome (IBS) are true EXCEPT that:
   a. it is a functional disorder.
   b. it is characterized by irregular flare-ups and remissions.
   c. it has a well defined, easily diagnosed cause.
   d. its major symptoms are abdominal pain, constipation and diarrhea.

2. When using fiber supplements to treat IBS, it is best to take them with:
   a. a minimal amount of fluids.
   b. a large amount of fluids.

3. Overuse of which of the following categories of OTC products is reported to trigger IBS symptoms?
   a. Antihistamines c. H-2-antagonists
   b. Antidiarrheals d. Laxatives

4. Which of the following characteristics is most helpful in differentiating IBS from organic bowel disease?
   a. IBS is characterized by abdominal pain that is relieved by defecation.
   b. IBS is characterized by anemia.
   c. IBS is characterized by bloody stools.
   d. IBS is characterized by severe weight loss due to excessive excretion of calories.

5. The proposed mechanisms of action for supplemental fiber in treating IBS include all of the following EXCEPT:
   a. fermentation of fiber's carbohydrate content.
   b. increased softness and bulk of fecal mass.
   c. increased concentration of fecal bacteria.
   d. increased intraluminal pressure.

6. Fiber is the mainstay in the treatment of IBS because it:
   a. decreases fecal transit time when it is too rapid.
   b. increases fecal transit time when it is too slow.
   c. does both of the above.
   d. does neither of the above.

7. Which of the following types of fiber is more effective for treating IBS?
   a. Soluble fiber
   b. Insoluble fiber.

8. Patients who experience the symptoms of IBS when they consume diary products most likely have a:
   a. calcitonin dediciency.
   b. galactosidase deficiency.
   c. lactase deficiency.
   d. renin deficiency.

9. Products that prevent gas formation from high fiber foods contain which of the following ingredients?
   a. Calcitonin c. Lactase
   b. Galactosidase d. Renin

10. Patients with IBS should be advised about all of the following EXCEPT:
   a. it cannot be self-diagnosed, but can be self-treated with OTC products.
   b. increased gas and bloating can occur early in therapy.
   c. adequate sleep, recreation and exercise are important.
   d. untreated irritable bowel syndrome inevitably leads to cancer.

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MARYLAND Pharmacist

VOLUME 75, NO. 3

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Embrace Change

Member Spotlight
Pharmacy and Motherhood

Labeling Changes
FDA Cracks Down on OTC Confusion

Pharmacy-Based Immunization
A Growing Trend in Pharmacy Practice

Improved Patient Compliance
Drug Calendars

Joseph A. DeMino, P.D.
MPhA's 1999-2000 President

MARYLAND PHARMACISTS ASSOCIATION

JULY / AUG / SEPT 1999

Maryland Pharmacists Association

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The Official Publication of the Maryland Pharmacists Association

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Do Unto Others...

The Golden Rule Of Better Service

The last time you got treated badly by a salesperson, did you curse the person under your breath, or did you stop to consider what you could have done to avoid the situation in the first place? Andrea Nierenberg, principal of The Nierenberg Group, a New York-based business consultancy believes that not enough of us do the latter. "When interacting with others, a lot of people walk around thinking, 'What am I going to get out of this?' " Nierenberg says. "But if you take the time to acknowledge and validate the other person, you can often turn a bad situation around." Below, she offers hints on getting better service from people.

Look them in the eye.

"Very often we don't look at people while we're talking to them, or we look away when they start to talk," Nierenberg notes. "That makes them feel hurt, or like a nonperson." People want to feel important, she says. "Looking at them lets them know you're paying attention to what they're saying."

Listen.

Customers often get defensive and interrupt when salespeople start talking, Nierenberg observes. "Instead, hold your tongue and listen to their point of view." Acknowledge what they're saying by paraphrasing it back; then add, "I understand how you feel, now let me explain how I see things." Nierenberg believes that by actually listening to others, you pay them the highest compliment: "People want to be heard."

Use people's names.

That's what those nametags are for! And yet most of us don't do this, probably because it feels a little awkward with strangers. Don't worry, says Nierenberg—after the first few times, it'll start to seem natural, and it pays off because people appreciate being acknowledged. Nierenberg cautions against overusing names, however: "You don't want to sound like a parrot. My rule of thumb is three times: at the beginning of the conversation, in the middle, and at the end."

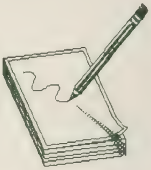
Find a way to compliment them.

Nierenberg stresses, though, that your praise must be sincere. "Think of something positive to say," she says. "You might tell them they're very detailed, that they've got great follow-through, or even something like, 'That color looks great on you,' or 'That hairstyle is terrific on you.' "

Say "please" and "thank you."

Of course our parents taught us this as children, but Nierenberg points out, "They're so basic, we forget." Remember that you're trying to get something from the assistants or salespeople you're dealing with, so "Thank people for going out of their way," she says. "Tell them you appreciate the effort."

Follow up in writing.



"I'm a great believer in the handwritten note," Nierenberg says. "Once I was trying to phone someone at a company to complain about a product, and I got through to his assistant. She was very difficult and wouldn't let me speak to her boss. During our conversation I got her name, and later I sent her a note telling her she was a great assistant because she was so good at screening calls! The next time I phoned, she was really sweet and open."

Using these techniques is really about developing the art of charisma, according to Nierenberg. "And that's important," she says. "People are people—treat them kindly and it usually comes back to you."

Nierenberg also stresses that you needn't follow all six tips immediately. "If you pick just two and start with those, you'll get better service," she promises. Then, try adding a new one—and when you get good at it, add another. Soon you'll have all six, and you'll have salespeople, waiters, and assistants eating out of your hand.

With permission from
Successful Meetings/May 1999

President's Commentary

Embrace Change

Joseph A. DeMino, P.D.

I would like to thank the members of the Maryland Pharmacists Association for giving me the honor and privilege of serving as your President. Your president last year, Jerry Herpel, has done an outstanding job in his efforts to deal with major issues facing our association and our profession in Maryland. These issues will be the basis of our goals for the coming year as we continue to seek solutions to problems and enhancements to our association.

Pharmacy is undergoing tremendous change. We must *embrace that change* or be trampled by it. As the elderly population grows, the number of prescription services needed by these patients also grows. Some estimates say that prescriptions will increase by as much as 45% by the year 2005. The number of pharmacists, however, will only increase marginally—about 6%. In order to meet the public need and demand for pharmacy services in this expanded market, we must see that the laws and regulations change to allow pharmacists to reach their full potential in patient care. This will include:

- The expanded or increase use of technology and pharmacy technicians
- Allowing pharmacists to enter into collaborative practice with medicine to improve patient care and outcomes
- Reimbursement for cognitive services

With the increase in the demand for pharmaceutical care and prescriptions at the retail community level, we must continue to work closely with the School of Pharmacy to ensure that pharmacy students receive more experience in community pharmacy prior to graduation in order to meet the public need. We must provide the School with more clerkship sites. This is an opportunity to help develop our pharmacists of the future.

The success of the MPhA will depend on two things: membership and participation. We must all do our part by participating in the activities of our association and reaching out to our colleagues.

In this coming year, we have much to do. With the growth and participation our membership, we can achieve our goals. ***Let us embrace change together***.

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Director's Column

What are the issues that concern the employee pharmacist?

Howard R. Schiff, P.D.
Executive Director

One principal task I must do as executive director is to increase membership. Today, most pharmacists work for someone else. Although independent pharmacy is still alive and kicking—the chains, hospitals, and long term care facilities are the largest employers of pharmacists in Maryland. Thus, it is no surprise that employees form the bulk of our members.

Membership in your state association shows you care about your profession. Pharmacy is what you have chosen to do with a large portion of your life. The association is the arena in which you can express your views; be informed on important and current issues; and influence the stand that the one association in Maryland which represents all facets of pharmacy takes on a particular issue.

MPhA is constantly trying to broaden our appeal to employee pharmacists. Any organization composed of volunteers must have an appeal for its prospective members. The questions I ask myself are: *"What are they concerned about?"* and *"What can we do for them?"*

Let us not be naive. I believe, long hours, lunch and bathroom breaks, understaffing, stress, and third party problems are some of the concerns.

I do not think that having an adversarial relationship between employer and employee is necessary. The real villain is the reduced reimbursement to pharmacies from managed care organizations and insurance companies. Perhaps we can start a dialogue between employers and employees which would help build stronger, more satisfying, and lasting relationships.

Let me know what you think—your concerns and suggestions. Please write, fax, or e-mail. Your anonymity is guaranteed. It is important that your voice is heard.

One of the most important things that the association can do is to provide a forum for free expression for all pharmacists.

Send comments to:
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Mental Clarity and *Gingko Biloba*

Gingko Biloba: The Mind Herb

Counseling Guide for Pharmacists

The gingko tree is the oldest tree, dating back about 200 million years. A deciduous tree, the gingko has fan-shaped leaves resembling those of a maidenhair fern; it can grow to heights greater than 100 feet. Extracts of *gingko biloba* have been used medicinally in China for more than 2,000 years to treat cerebral vascular conditions, asthma and coughs.

Drawing by C. H. Wooley, Point Reyes, CA

Particularly in the elderly, cerebral vascular insufficiency is a growing problem, resulting from the high prevalence of atherosclerosis. And as the elderly population increases, so will the incidence of atherosclerosis and related conditions.

Gingko biloba is among the leading phytomedicines prescribed by physicians in Germany and France, where it is used primarily for vascular insufficiency. More than 50 double-blind trials have indicated at least some benefit from this herb.

The German Commission E has approved *gingko biloba* for "symptomatic treatment of disturbed performance in organic brain syndrome within the regimen of a therapeutic concept in cases of demential syndromes"—targeting the principal symptoms of memory deficits, disturbances in concentration, depressive emotional condition, dizziness, tinnitus and headache associated with primary degenerative dementia, vascular dementia, and mixed forms of both conditions.

Results of a multicenter study of *gingko biloba* were published in *JAMA* (278:1327-1332, 1997). The study included 202 patients with Alzheimer's disease, who were given either *gingko biloba* (120 mg/day) or placebo for one year. Significant improvements in mental function were seen in 64% of patients taking *gingko biloba*, and no side effects were reported. The study concluded that gingko can safely improve cognitive performance and functional skills in patients with Alzheimer's dementia.

Standardized extracts of 24% gingko heterosides (flavone glycosides) have been used most commonly in clinical trials. Doses range from 40-80 mg, t.i.d. Side effects with gingko are rare and include gastrointestinal upset, headache and allergic skin reactions.

For more information on *gingko biloba* and other herbs, contact The American Botanical Council (512-331-8868) or the Herb Research Foundation (800-748-2617).

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Member Spotlight

Pharmacy and Motherhood

Ruth Blatt, P.D.

"Baltimore County Schools will be opening two hours late." These are some of the most unsettling words that I can hear on a snowy winter morning. Now I have to make some quick arrangements. Someone else needs to drive carpool, and who will make sure the other two kids get on the bus safely? Three kids, three different schools, three different schedules...what's a working mother to do? Life as a retail pharmacist and a mother surely keeps you on your toes.

I remember when I was in pharmacy school, people used to say "What a great profession that is for a woman!" That used to bother me. I wanted to choose a great profession—what difference did it make if I was a woman? But many years later, I can appreciate what they meant. I've chosen a great profession, and for the most part, motherhood and pharmacy make a pretty good alliance. I've had enough flexibility to take the time to raise a family and still maintain good standing in the profession.

I planned things pretty well. After graduating the University of Maryland School of Pharmacy I worked for five years before deciding it was time to start a family. I continued to work full time as long as I could, reducing my hours as the date for the blessed event came closer. After my son was born, (and two daughters in the years to follow), I was able to continue working in the same position, as a part time employee, until I felt I could re-enter the full time world of retail pharmacy once again. At this point, I was offered the position of pharmacy manager at a new NeighborCare Pharmacy that was being built three miles from my home. I couldn't have been given a more convenient location. I was able to negotiate hours that allowed me to drive my carpools and be home with my children in the evenings and on weekends. Now, it certainly isn't easy to be at work when the kids come home from school and I'm sure Dr. Laura wouldn't approve, but I've been able to balance both jobs. One of the keys to my success has been a wonderful woman who comes into my house to watch the kids. Being a pharmacist, I don't think I ever could have relied on traditional day care. They don't have late enough hours, and how could I explain to my employer that I couldn't take my toddler to day care because he had a cold so I can't come to work? The answer had to be day care in my home. The expense is greater, but for me, it was much more reliable.

There is a rather large "guilt factor" when you are a pharmacist and a mother. The toughest circumstances I've encountered being a working mother have been missing field trips and turning down requests for volunteering in my kids' classrooms. The schools don't seem to understand that some people need more than a week's notice to be able to arrange for relief coverage for a field trip. However, I have had some fun in the schools. The young classes love to hear my "My Mommy's a Pharmacist" presentation. You can hear the pride in my children's voices as they are allowed to introduce their guest speaker to the class. My kids sit there with huge smiles on their faces while their class watches me make capsules, triturate powders and especially fill ointment tubes. Those are the days when my two worlds come together, and I'm sitting on top of both of them.

Often, I feel like I live two separate lives and "never the twain shall meet." I'm famous for getting to work, and totally blocking out anything not work related. For example, a paper needs to be copied for one of the children's homework. Well, someone better call and remind me or odds are, it won't get done. When I'm at work, my Mommy hat gets left at home and when I'm involved with the kids, I try to leave the pharmacist hat at work. That part is easier said than done. Being the manager at a retail store, matters sometimes need to be taken care of "after hours." That's where the separate lives clash. The family wants my undivided attention when I'm at home, and they really deserve that. It's sometimes difficult, however, to just "turn off the pharmacist switch" when I get home.

Working full time and being a mother doesn't allow much time for other endeavors. There are so many other worthwhile activities that call out to me. My synagogue has activities and needs volunteers, MPhA is always looking for members to participate in committees, community groups are always meritorious and then where is the time to take care of me? I've found that it's important to sort out your priorities and make sure that the items at the top of the list are completed. After that, you do the best you can and everything seems to fall into place. I've had to learn to say "no" when I was being asked to do too much. I think people appreciate when you tell them honestly that you have too much on your plate at that time.

Though at times life seems overwhelming, I think that motherhood and a career in pharmacy can make good partners. Now I have to run, someone is waiting to be tucked in!

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Competing for the Future

Melvin F. Baron, Pharm.D., MPA

Abstract

Pharmacies must look for strategies to increase profits and market share in an era of continuous change. Updating operating procedures, expanding the products and departments in the pharmacy, updating the look of the pharmacy, expanding into home shopping opportunities and incorporating services for disabled patients are a few ideas to help strengthen a pharmacy's position in the market. Abundant opportunities are available in pharmacy for those willing to investigate and find a niche in their own community. Attention must be paid to the changing market forces to compete and increase profits and market share.

Introduction

The time for planning your future is NOW. Tom Peters, in his book "*Thriving on Chaos*," talks about how change has become a constant in our lives. He maintains that we must welcome change and innovation as vigorously as we fought it in the past. To survive in today's dynamic environments, Peters says we must develop a capacity for continuous change.[1] Pharmacists are faced with an era of continuous change in patient care and pharmacoeconomics. Our relationship with our patients, peers and society is being redefined.

The profile and psychology of a pharmacy practice has been transformed by a wide variety of factors including changing buying habits due to managed care, an aging population, more working women, greater ethnic diversity and an uncertain economic future. Rising health care costs have led to more aggressive cost-containment in most public and private health insurance programs. Even though studies have documented the value of the pharmacist as a health care professional, it is difficult to obtain adequate compensation from public and private third party administrators for providing pharmaceutical care services.

Similarly, society is going through a massive shift. The information revolution no longer uses a hierarchical model. Workers at all levels of the organization are empowered by both technology and information. This increased participation, more shared decisions, and more decisions at the point of service mean increased collaboration and shrinking hierarchies.

Some analysts predict that by the year 2000 there will be only a few major pharmacy chains left and a shrinking number of independent pharmacies. As profit margins narrow due to increased competition and managed care, large chains must enhance operating efficiencies by spreading costs over more stores and using their buying clout to get better prices for merchandise. Independent pharmacies must also enhance their operating efficiencies, develop alliances with buying groups, collaborate with other independent pharmacies, and consider merging local pharmacies to create regional networks. Readily adaptive companies stress sharing information and power across the organization, have healthy alliances with suppliers and customers, and have the ability to quickly respond to changing market conditions.

There are a number of strategies to increase profits and market share. Using these can increase a pharmacy's chance of success in the face of constant change. Updating operating procedures, expanding the products and departments in the pharmacy, updating the look of the pharmacy, expanding into home shopping opportunities, and incorporating services for disabled patients are included in these strategies.

Operation Updates

To redirect the focus of the pharmacy, develop a mission statement which eliminates or de-emphasizes activities not essential to your mission. One must examine the internal bureaucracies and consider paring down and reducing the number of layers within your organization. Hire outside companies to provide services that you do not need to control directly. For example, activities that can be outsourced may range from running computer operations to janitorial services. A catalog you wish to provide to your customers can be developed by a specialist partner who you can hire that will select the merchandise, mail the catalogs, and fill the orders if you desire. Begin to rethink and simplify all standard operating procedures. Eliminate any procedure that does not enhance quality service or care.

Even big, complicated organizations can be flexible, especially if employees have clear directions and the autonomy to make the changes they need. Pharmacy personnel should be cautioned to not let technology replace the personal touch. Many pharmacy owners and chains may be tempted to go to an outside firm for ideas or management tips. Before you hire the high priced "experts," give your own team a chance to offer suggestions to streamline workflow and reward them accordingly.

Product Expansion

Expanding the product lines and services provided can open the pharmacy to new patient populations. When these patients come for the newer specialized services or products, they will often also take advantage of the standard services such as prescription and over the counter sales. The key factors in developing new departments in your pharmacy are product knowledge, selling skills and knowing your patient/customer needs. Look for products that can cut your costs, yet still provide superior service to your patient. A list of suggested products and departments is outlined in Appendix 1.

Private label products should also be utilized. The pharmacy should create or expand this business, keeping in mind key issues as value, quality and exclusivity. Areas beyond vitamins should be considered.

Home test kits, diabetic products and wound care are growing niche product lines that can help pharmacies reduce third party reimbursement worries. The convenience of home diagnostics is so attractive that revenues are expected to jump from $1.44 billion in 1997 to $2.17 billion by the year 2000. According to Frost & Sullivan, a marketing research company, home tests for pap smears, noninvasive human immunodeficiency virus (HIV) and osteoporosis are scheduled to be introduced into the marketplace over the next few years.[2] Including these products in your pharmacy can take advantage of a blossoming market.

Customer interest in natural remedies and natural beauty care products is shattering all sales expectations. Herb growth is robust. Industry forecasts total herbal supplement sales of more than $1.6 billion by the year 2001.[3] The steady sales escalation reflects Americans' overall concerns about wellness, self-care and medical cost containment. Again, the pharmacy ready to confront change would look to this new product line for increased sales.

Pharmacists can play a crucial role in educating consumers on the proper use of herbs and in alerting the user to potential drug interactions with prescription medications as well as over-the-counter products. With the growth of herbal and complementary medicine, now is the critical time for pharmacists to take a proactive role with their patients who are using those products.

Appendix 1: Other Suggested Products and Departments

A. Ostomy care
   1. Skin care
   2. Wound management
B. Surgical supplies
   1. First aid
   2. Physician supplies
C. Incontinence products
   1. Urological
   2. Fecal
D. Supports and appliances
   1. Orthopedic fittings
   2. Mastectomy supplies
   3. Sports medicine
E. Respiratory therapy
   1. Liquid oxygen systems
   2. High pressure oxygen
   3. Portable oxygen
   4. Nebulizers
   5. Suction
F. Durable medical equipment
   1. Simple type (i.e. canes, crutches)
   2. Rehabilitation equipment
   3. Exercise/sports type
G. Electro-medical
   1. Trans-cutaneous electrical nerve stimulation (T.E.N.S.) / Pain management
H. Daily living aids for handicapped persons
   1. Reaching aids
   2. Switches
   3. Utensils
I. Diagnostic devices and self-care
   1. Stethoscope
   2. Glucose testing
   3. Urine analysis
   4. Pregnancy tests
   5. Cholesterol tests
   6. HIV tests
   7. Urinary tract infection (UTI) care
J. Nutritional therapy
   1. Health food
   2. Vitamins and mineral supplements
   3. Herbal products
   4. Enteral feeding
   5. Total parenteral nutrition
K. Home intravenous therapy/chemotherapy
   1. Hydration
   2. Antibiotics
   3. Pain management
   4. Total parenteral nutrition (TPN)
L. Compounding pharmacy
   1. Non-sterile products
   2. Sterile products

Pharmacy Remodeling

Revitalizing the pharmacy by making pharmacy interiors more comfortable and inviting, as well as changing the décor, will invite patients back over and over. A private counseling area for patients is one feature which will update the pharmacy.

Pharmacy retailers need to consider selling more cash-and-carry items in this time of shrinking reimbursement. To aid in achieving this, attention must be paid to space management, traffic flow, display and packaging and good old-fashioned sales skills. A good floor plan can guide patients/customers to the right department regardless of whether they are looking for a must-have item or making an impulse purchase. Impulse purchases can increase cash sales; pharmacies need to be set up so customers can readily see what they "can't live without." A relatively small change in traffic flow can result in substantial sales increases.

Shopping at Home

Home shopping has become a $25 billion a year business through traditional mail order catalogues, home shopping networks, infomercials, computer e-mail, the Internet and soon, by interactive television. The major cable television shopping channels have special life style channels that cater to affluent shoppers who are interested in health and fitness. This is a way to expand your sales base by providing customers and patients with more options to buy. Catalogues can also be utilized, even those featuring only private label merchandise.

Companies are realizing that if they do not take advantage of online sales, their competitors will. Forrester Research, a Cambridge, MA firm that follows online commerce, estimates that consumers spent $2.4 billion on the Internet last year. Forrester forecasts that 1998 sales will double last year's sales to reach an estimated $4.8 billion and reach $3.2 trillion by 2003.[4]

Services for the Disabled

There are many areas in which the disabled customer can be better served. Developing employee sensitivity training programs and improving access to your facility are two ways to improve service to these patients. Telephone numbers allowing the pharmacist to communicate with the hearing-impaired patient via text telephones (TTY) are also helpful. This communication with the pharmacist can ultimately benefit the patients' health by increasing access to the health care system.

Summary

Pharmacy is diverse and offers abundant opportunities for those willing to investigate available opportunities, find their niche and practice to meet the needs of their own community of patients. By doing this, the pharmacy can compete and increase both profits and market share.

Pharmacy is faced with a mix of rising costs, shrinking revenues and new competitors. Develop a process of redesigning your operation that will lead to higher levels of productivity, keeping the best and changing the rest. As President Franklin D. Roosevelt once said, "To reach a port, we must sail—sail, not lie at anchor—sail, not drift." You cannot succeed by doing the exact same thing as your competitor. You need to differentiate yourself—offer something else. Pay attention to the ever-changing market forces, so you can jump on new opportunities and discard losing propositions.

About the Author

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A Look Back

A PRIEST LOOKS AT PHARMACY

Article appeared in The Maryland Pharmacist in May 1947

In an address at St. Joseph, Louisiana, reported in the May 5 issue of the N.A.R.D. JOURNAL, Reverend John P. Quinn, S.S.J., pictured the relationship of the druggist and his customers as "a beautiful tapestry" which is "interwoven on a background of black and white—namely, sorrows and joys."

"The career of a pharmacist," said the priest, "brings one closer to real life than falls to the lot of most men . . . The true pharmacist leads a life of endless labor, unceasing vigil, and inexhaustible research, working among all classes of people, both rich and poor, in plague-ridden villages, or on the battlefield . . . He follows the precept of an ancient Hebrew philosophy; he does justice, loves mercy, and walks humbly with the sick and with God."

Along economic lines, Father Quinn advised druggists, "Be practical, produce more, and produce it efficiently . . . If you don't, the purchasing power of billions will be dissipated in inflation . . . Keep the customers you have and add more, if you are to do for your country and yourselves a full measure of service."

Then he challenged the druggists, "What shall you do to stop the trend away from professionalism? What are yours plans for curbing this radical departure from what you hope the true American pharmacy or drug store shall be?... Some place and somewhere there must be a line of demarcation. The establishment of that line is the responsibility of the leaders in pharmacy."

THE PUBLIC'S HEALTH-YOUR FIRST CONCERN

HEART DISEASE AND THE LIFE SPAN

Article appeared in *The Maryland Pharmacist*, June 1950

Every year, despite a lengthening life span, heart disease is taking an increasing toll of those under 65. As a result of the strides made by medical science in the past four decades in bringing under control the infectious menaces such as typhoid, tuberculosis, and the childhood diseases, formerly outstanding killers, the average life expectancy has been increased from 49 years in 1900 to that of 67 years today. Yet each year about 250,000 persons die before reaching age 67—as a result of heart disease.

Implicit in the longer life now promised the average individual is that more years of usefulness are required today of his heart than was the case in times past. A new emphasis is needed on conserving the vigor and "staying power" of life's vital pump.

A large number of deaths due to heart disease, particularly in early and middle adult life, are preventable. While degenerative heart disease is a hazard of old age and is impossible to prevent entirely, much can be done to postpone its onset and to slow down its progress among those in the middle-aged and younger groups who constantly are adding to the growing number of cardiac cases.

Early discovery is of the greatest importance, implying not only prompt institution of therapy, but often the alteration of a too strenuous pace of life in time to prevent serious damage to a heart already beginning to gasp from its overload. Early steps to reduce weight in obese persons may be necessary in order to relieve the added burden placed upon the heart by excess weight.

Since so much of the value of treatment of heart disease depends upon the patient himself, an informed public must be the basis for an intelligent approach to the problem of the individual and the community. In this the pharmacist is a valuable ally of the physician, not only in getting a patient to a doctor, but as a source of reliable information to the community, since it is to the pharmacist that people often turn first with their complaints.

Treatment of heart disease is not one but a number of problems, based on the type of heart disease. The causes and the conditions of these types vary, but their effects are the same—all sap the endurance power of the heart. In the search for cure the problems are being dealt with on broad fronts—by surgery, diet, drugs, antibiotics, and even by psychotherapy.

As a result of modern surgical pioneering, the scalpel—on the tip of a surgeon's finger—is now probing the heart itself to correct the ravages of rheumatic fever and the malformations of congenital defects, both important causes of crippling heart disease.

Similar advances are being made by chemotherapy. Sulfa drugs are forestalling rheumatic fever and preventing damage to delicate heart valves. Penicillin is curing 70 to 75 percent of cases of bacterial endocarditis which formerly were 99 percent fatal. New drugs are being used to reduce blood pressures that have reached dangerous heights. Dicumarol and heparin, by lowering the clotting ability of the blood, are reducing the complications that follow a coronary attack.

Medical science is thus actively taking up the challenge posed by heart disease. With an increasing fund of knowledge resulting from added support for research, medical science is mapping out new areas of prevention, treatment and cure. But, along with an increased life span and the promise of even more research progress yet to come, an important responsibility still rests with the individual: This is to be alert in bringing symptoms to the attention of a physician early. In this chain of communication the pharmacist plays an important and vital role.

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Labeling Changes:
FDA Cracks Down on OTC Confusion

Compiled by Neil V. Smith, Pharm.D. Candidate

March 11, 1999 - The Food and Drug Administration announced new, easier-to-read labels for all OTC medicines. Vice President Al Gore and Health and Human Services Secretary Donna E. Shalala announced the new landmark regulation that requires OTC drug products to use a new label with larger print and clearer language, making it easier for consumers to understand product warnings and comply with dosage guidance.

The regulation calls for a standardized format in an effort to improve public understanding of the product labels. "Written in plain language and presented in a user-friendly format, the new label conveys essential information for patients and consumers," said Secretary Shalala. The new regulation, initially proposed in February 1997, is the end product of almost 2,000 comments and years of agency work with consumer and industry groups.

> *With this new regulation I am unveiling today, we will ensure that the labels on medicine we buy over the counter are no longer written in language that is over our heads. Starting here and now, when children wake up sick in the middle of the night, parents won't have to read a dictionary to read the directions, and people will not need a magnifying glass to find out what is in their medicine.*
>
> Vice President Al Gore
> March 11, 1999

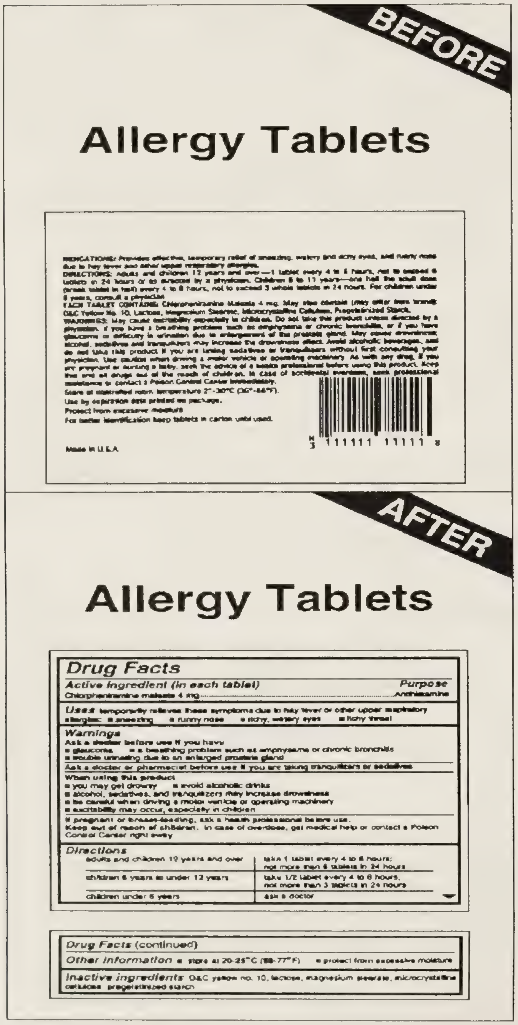
Each year, Americans purchase five billion OTC drug products for a wide variety of ailments, ranging from headaches to arthritis to sore throats. Approximately 100,000 OTC drugs can be used to treat routine illnesses without a prescription, requiring consumers to make their own judgement about what drug to take, how to take it, and whether or not to give it to their children. The FDA hopes that the new labeling will help to reduce and avoid adverse drug reactions by providing the public essential "drug facts" that are easier to understand.

The new labels:

- *Require a standardized, easy-to-follow format.* The regulation requires labels to list ingredients in the same place on every product and explain which ingredients are used to treat specific symptoms;
- *Include critical information about the drug product.* The new label will clearly present a drug's ingredients, dose, and warnings, making it easier for consumers to understand essential information about the medication's expected effectiveness and associated risks, determine appropriate dosage for children and adults, and compare the content of different products;
- *Increase the size of the label so it can be easily read.* The regulation specifies the minimum type size for labels in order to make them easier to read, based on studies that included older people and demonstrated how important type size is to reader comprehension;
- *Allow for a modified format for smaller packages.* The regulation also allows packages that are too small to use standardized label to use a modified version that includes the most essential information on the new label.

Among these changes, one particular victory for pharmacists is apparent. The new labeling will require that all drug products that contain warnings concerning drug-drug or drug-food interactions be listed under the subheading, "Ask a doctor or *pharmacist* before use if you are..." However, the subheading can leave out "or pharmacist" if the product warning is for a preexisting condition or symptom.

The new labeling will begin appearing on the shelves within the next two years. According to the regulations, all OTC drugs will be required to adopt the new labeling within the next six years. Below is an example of an old versus new label. It is important to note that this example is reduced to fit this page and is not actual size. The regulations state that the minimum type size must be no smaller than 6 point type, the type size of this sentence


BEFORE
AFTER

Allergy Tablets

INDICATIONS: Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.
DIRECTIONS: Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician. Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician.
EACH TABLET CONTAINS: Chlorpheniramine Maleate 4 mg. May also contain (may differ from brand): D&C Yellow No. 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch.
WARNINGS: May cause excitability especially in children. Do not take this product unless directed by a physician, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.
Store at controlled room temperature 2°-30°C (36°-86°F).
Use by expiration date printed on package.
Protect from excessive moisture.
For better identification keep tablets in carton until used.

Made in U.S.A.

Allergy Tablets

Drug Facts

Active ingredient (in each tablet) — *Purpose*
Chlorpheniramine maleate 4 mg .... Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings
Ask a doctor before use if you have
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives
When using this product
■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

Directions

adults and children 12 years and over	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children 6 years to under 12 years	take 1/2 tablet every 4 to 6 hours, not more than 3 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)
Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

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Although we Americans spend billions of dollars every year on medicines, many of us don't know what to expect from them or how to take them properly. Taken correctly, medications can save lives. Taken incorrectly, even the most expensive medicine may not work–or may even be harmful.

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APhA

A public service message from the
American Pharmaceutical Association
The National Professional
Society of Pharmacists

Pharmacy-Based Immunizations

A Growing Trend in Pharmacy Practice

By Neil V. Smith, Pharm.D. Candidate
University of Maryland School of Pharmacy

In 1998, Maryland Legislature debated two bills. One was about collaborative practices, while the other was about medicine administration. Although both bills failed to be passed into Maryland law, their content was a reflection of a growing trend among pharmacists' legal protocols in other states. To date, pharmacists are authorized to administer immunizations in thirty (60%) states. Among those thirty states, only twenty (66%) of them have pharmacists actively administering immunizations.

According to the American Pharmaceutical Association (APhA) the states that currently allow pharmacists to administer immunizations are[†]:

Alabama*
Alaska
Arkansas*
California*
Colorado
Delaware
Georgia*
Idaho
Illinois*
Indiana*
Iowa*
Kansas
Kentucky*
Michigan*
Mississippi*
Missouri*
Nebraska*
Nevada
New Mexico
Ohio
Oklahoma*
Oregon
South Carolina*
South Dakota
Tennessee*
Texas
Utah
Virginia*
Washington*
Wisconsin*

*States known to have pharmacists actively administering immunizations.
[†] Based upon survey of association executives.[1]

Why are only 66% of the states that have legal authority to administer immunizations actually performing this valuable service? The answer is probably a collection of reasons. One possible answer stems from the lack of education. Various professional organizations have countered this with readily available certification programs, seminars, and guidelines. For example, the American Society of Consultant Pharmacists (ASCP) has published guidelines for pharmacists' active participation in comprehensive immunization and is spearheading the 100% Immunization Campaign slated for full implementation this fall.[2-3] Additionally, APhA has a self study program entitled "Pharmacy-Based Immunization Delivery a National Certificate Program for Pharmacists."[4] Using these resources to further the knowledge base of pharmacists will ultimately lead to increased numbers of pharmacists actively administering immunizations.

As previously mentioned, Maryland legislation failed to allow pharmacists the legal ability to administer immunizations. Part of the reason for the bill's failure resides with the nurses and physicians. Nurses view this as a violation of the nurses' rights. Therefore, it is no surprise that despite the much public good Pharmacy-Based Immunization could create, nursing organizations are against it. Physicians also view Pharmacy-Based Immunization as a threat. Unlike the nurses, however, physicians perceive the threat as a reduction of income and patient clientele. Some people actually would prefer to obtain their immunizations from the pharmacist. However, this is not the focus of Pharmacy-Based Immunization. Rather, Pharmacy-Based Immunization provides a service to the population of people that would otherwise go without immunizations because of financial circumstances, poor healthcare accessibility, or a combination of both.

John Grabenstein, a well known vaccination expert, testified before the Maryland House of Delegates in support of the medicine administration bill. Grabenstein related several shocking statistics. In Maryland, 1,000 to 1,600 people die each year from influenza and pneumococcal disease. Approximately 80% of these deaths occur to those 65 years or older. Indeed, influenza and pneumococcal disease rank sixth in cause of death; fifth among the elderly. Grabenstein further claimed that, "Tens of thousands of parents and grandparents are dying prematurely."[5]

For years now, pharmacists have been viewed by the public as trustworthy. In fact, a study shows that "between 50 and 94% of people who receive a pharmacist's recommendation to be immunized accept that recommendation."[6] It is also true that pharmacists are the most accessible health care professional in rural areas.[7] Prudence, therefore, would suggest pharmacists enlist in the immunization cause to better the public's knowledge and health.

But what of the legal ramifications associated with medicine administration? As long as the state recognizes medicine administration by pharmacists as being legal, then it has become part of the pharmacist's scope of practice. This means that the physician is no longer liable. Furthermore, vaccine administration is conceptually similar to drug dispensing. The end result is the same. The patient gets the medicine or vaccine. It is the pharmacists' responsibility to ensure self protection through patient education about the drug or vaccine.[8]

Maryland pharmacists need to rally in support of making pharmacy medicine administration a legal practice. Such a practice requires education and entrepreneurship. Resources are available to assist in the education process. Maryland pharmacists should attempt to work with other health care professionals and focus on the public's need for immunization. Research shows that pharmacists are the most accessible health care professional. Thus, Maryland pharmacists must take the responsibility and be prepared to counsel and inform the public of vaccine safety and the need for immunization.

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Oath of a Pharmacist

At this time, I vow to devote my professional life to the service of mankind through the profession of pharmacy.

I will consider the welfare of humanity and relief of human suffering my primary concerns.

I will use my knowledge and skills to the best of my ability in serving the public and other health professionals.

I will do my best to keep abreast of developments and maintain professional competency in my profession of pharmacy.

I will obey the laws governing the practice of pharmacy and will support enforcement of such laws.

I will maintain the highest standards of moral and ethical conduct.

I take these vows voluntarily with the full realization of the confidence and responsibility with which I am entrusted by the public.

Baltimore still has high rates

Syphilis, gonorrhea at all time lows; other STDs continue to spread widely

Syphilis and gonorrhea have reached all-time lows, but a number of cities in the South and Northeast continue to battle high rates of both diseases, according to data release recently by the Centers for Disease Control and Prevention (CDC).

Fifteen cities, including Baltimore, share the grim distinction of leading the nation in reported rates of both sexually transmitted diseases (STDs). The cities that made the list for highest rates of both gonorrhea and syphilis in 1997 are (in alphabetical order) Atlanta, Baltimore, Birmingham, Chicago, Detroit, Memphis, Milwaukee, Nashville, Newark, New Orleans, Norfolk, Oklahoma City, Richmond, St. Louis and Washington, D.C.

Baltimore ranked first in both syphilis and gonorrhea rates. Washington, D.C. seventh in syphilis and second in gonorrhea rates.

Gonorrhea and syphilis, the STDs we have been battling the longest, are now primarily isolated geographically, but other disease such as chlamydia, herpes and human papilloma virus (PV) remain extremely widespread, according to Helene Gayle, M.D., M.P.H., director of CDC's National Center for HIV, STD, and TB Prevention.

Syphilis rates are currently at the lowest level in history, and half of reported cases are concentrated in just one percent of the U.S. counties. Historically low rates and geographic concentration, recent advances in treatment and genetic sequencing, and the basic characteristics of the disease (such as the absence of drug-resistant strains and non-human sources of infection) signal that syphilis can be eliminated.

Syphilis elimination efforts are critical to improving infant health, slowing the spread of HIV infection and reducing racial disparities in health. Untreated syphilis during pregnancy results in infant death in up to 40 percent of cases and over 65 percent of cases of congenital syphilis are among African Americans. Moreover, syphilis is believed to be accelerating the spread of the HIV epidemic, particularly in communities of color. Given the disproportionate toll of the disease among African Americans, syphilis and its preventable consequences constitute one of the most glaring racial gaps in health status in the United States, according to the CDC.

However, STDs still remain one of the most under recognized health threats. Latest estimates indicate that 15 million Americans become newly infected with an STD each year.

The national improvement of the prevention and treatment of STDs is a priority for the CDC, according to its director, Jeffrey Koplan, M.D., M.P.H. The detection and treatment of chlamydia is another urgent priority for national STD prevention efforts.

CDC receives more reports of chlamydia each year than any other infectious disease. While the disease can be easily treated and cured if detected early, it often has no symptoms and goes undiagnosed. Untreated, chlamydia can lead to severe health consequences for women, including infertility and potentially fatal tubal pregnancies.

According to CDC, the toll of chlamydia can be reduced with existing knowledge, technology and treatments. Figures show a significant reduction in the percentage of young women with chlamydia in areas with widespread screening and treatment programs. These programs currently reach only 50 percent of women at risk in 20 states and less than 15 percent in 30 states.

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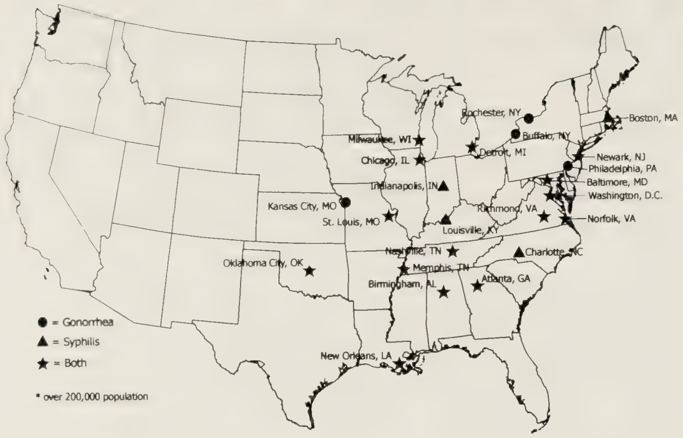
Top Twenty U.S. Cities* by Gonorrhea and Syphilis Rates


Rochester, NY
Boston, MA
Buffalo, NY
Milwaukee, WI
Detroit, MI
Newark, NJ
Chicago, IL
Philadelphia, PA
Baltimore, MD
Indianapolis, IN
Washington, D.C.
Kansas City, MO
Richmond, VA
St. Louis, MO
Norfolk, VA
Louisville, KY
Nashville, TN
Charlotte, NC
Oklahoma City, OK
Memphis, TN
Atlanta, GA
Birmingham, AL
New Orleans, LA
● = Gonorrhea
▲ = Syphilis
★ = Both
* over 200,000 population

Top 20 U.S. cities by gonorrhea and syphilis rates

Gonorrhea*

City	Number of Cases	Rate per 100,000 population
1. Baltimore, MD	6,693	991.0
2. Washington, DC	4,557	838.9
3. St. Louis, MO	**2,901**	**825.2**
4. Rochester, NY	1,867	769.6
5. Atlanta, GA	5,468	761.2
6. Detroit, MI	7,887	755.2
7. Richmond, VA	1,466	739.4
8. Newark, NJ	1,967	688.6
9. Norfolk, VA	1,462	626.3
10. New Orleans, LA	2,743	575.5
11. Memphis, TN	4,876	562.1
12. Oklahoma City, OK	2,080	471.9
13. Birmingham, AL	3,104	468.9
14. Kansas City, MO	**2,000**	**448.9**
15. Philadelphia, PA	6,504	440.1
16. Chicago, IL	11,498	393.0
17. Nashville, TN	2,050	383.2
18. Minneapolis, MN	1,430	371.1
19. Buffalo, NY	1,172	362.4
20. Milwaukee, WI	3.303	358.1

* Rate for U.S.: 122.5

Syphillis*

City	Number of Cases	Rate per 100,000 population
1. Baltimore, MD	669	99.1
2. Memphis, TN	343	39.5
3. Nashville, TN	203	37.9
4. Atlanta, GA	204	28.4
5. New Orleans, LA	132	27.7
6. Richmond, VA	49	24.7
7. Washington, DC	117	21.5
8. Norfolk, VA	44	18.8
9. St. Louis, MO	**60**	**17.1**
10. Oklahoma City, OK	73	16.6
11. Birmingham, AL	107	16.2
12. Louisville, KY	107	15.9
13. Chicago, IL	346	11.8
14. San Juan, PR	99	11.4
15. Detroit, MI	101	9.7
16. Boston, MA	52	9.3
17. Milwaukee, WI	84	9.1
18. Newark, NJ	26	9.1
19. Indianapolis, IN	71	8.7
20. Charlotte, NC	48	8.0

* Rate for U.S.: 3.2

Statistics from the National Center for HIV, STD & TB Prevention Centers for Disease Control and Prevention

Rx AND THE LAW

By Don McGuire, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

"The Pharmacy's Duty to Protect Confidentiality"

When can a pharmacist release a patient's prescription records? This is a common question which needs to be correctly answered. Failure to do so could result in an action for damages against the pharmacy, as Rite Aid discovered in Washburn v. Rite Aid Corp.[1], a Rhode Island case.

The Washburns were in the process of a contested divorce when Mr. Washburn's attorney subpoenaed Mrs. Washburn's prescription records from Rite Aid. The subpoena requested a representative from Rite Aid bring to court the records for both Mr. and Mrs. Washburn for the last five years. The clear language of this type of subpoena in Rhode Island requires the pharmacy representative to bring the requested records to court and then release them as ordered by the court. However, Rite Aid's usual practice was followed in this case. Unfortunately, many pharmacies would handle a subpoena in the same way Rite Aid did. Rather than bring the requested records to the deposition as stated in the subpoena, copies of the records were mailed directly to Mr. Washburn's attorney. There was no release received from the wife or her attorney for this action.

The Court concluded that this was an unauthorized release of confidential records. In its decision the Court said:

> "Indeed, the Confidentiality Act presumes that each and every one of these records is confidential and should not be disclosed except pursuant to valid legal process.
>
> Moreover, mere receipt of a valid subpoena does not negate this privilege; much less does it justify publication of the records to the person subpoenaing them or to anyone else."[2]

The pharmacist and the pharmacy must know when it is proper to release prescription records. The safest way is to have a valid, written authorization from the patient whose records are being requested. Rite Aid could have requested such a written authorization from Mr. Washburn's attorney, or from the wife's attorney, but did neither. Another proper method would be to turn over the requested records when ordered to do so by a court order. As this case shows, a subpoena is not a court order. Rite Aid did not act under court order nor pursuant to a valid release, and as a result, could be held liable for damages resulting from the improper release of confidential records.

There are some situations, however, where it is proper, and even necessary, for a pharmacist to disclose patient information. A pharmacist may release prescription and health information to a patient's treating physician when the information is necessary for the patient's medical care. For example, a pharmacy receives a call from the local emergency room. Mrs. Jones was just brought in unconscious, but a prescription vial with the pharmacy's label on it was found in her pocket. The ER wants information on what medications the pharmacy provides to Mrs. Jones. The pharmacy can legally provide this information to aid the emergency physician in treating Mrs. Jones.

It is important that everyone in the pharmacy understands that prescription records are confidential and understands the requirements for each employee to maintain that confidentiality. One way to highlight this is to have each employee read, understand, and sign an "Understanding of Confidentiality" statement. All requests for prescription records should be forwarded to the pharmacist or manager for handling. Requests should be reviewed to insure that the request is legally valid.

(***Note**: To request an "Understanding of Confidentiality" statement, pharmacists may call Pharmacists Mutual Insurance Company at **(800) 247-5930 (ext. 26)**. This "Understanding of Confidentiality" statement is not designed as a legal document, but as a method of emphasizing to each pharmacy employee the importance of confidentiality. Pharmacists should remember the law of confidentiality and release differs with each state. All pharmacists are urged to consult with an attorney in their state prior to using any form.*)

©Don McGuire, R.Ph. is a Professional Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorney and insurance company for specific advice. The Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

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[1] Christine Washburn v. Rite Aid Corp., d/b/a Rite Aide Pharmacies, 695 A.2d 495 (R. I. 1997)

[2] *Washbum*, 695 A.2d at 500

The Complexities of Borderline Personality

Borderline Personality Disorder (BPD) is a serious mental illness characterized by intense emotional instability, extreme impulsivity, frequent conflicts with others, feelings of emptiness, continual attempts to avoid abandonment or perceived abandonment, and irrational anger and/or raging. Many patients with this disorder attempt suicide, and about 8-10% of them succeed. Most patients are highly emotionally vulnerable, as they lack the skills necessary for regulating emotions. BPD is a Diagnostic and Statistical Manual (DSM) condition believed to result from a biological disorder of the emotional regulation system, a genetic predisposition, or environmental factors—or a combination of these three factors.

The condition affects about 2-3% of the general population, 10% of the psychiatric outpatient population, and 20% of the psychiatric inpatient population. It usually coexists with other illnesses, the most common being mood disorders, post-traumatic stress disorder, panic/anxiety disorders, substance abuse (more than half the patients with BPD have a problem with substance abuse), attention deficit disorder, obsessive-compulsive disorder, or multiple personality disorder.

Nearly 75% of BPD patients are women, and more than half of them have a history of physical or sexual abuse. This disease is severe, chronic and persistent, and it presents a major challenge to both health care professionals and patients because there is no single, ideal treatment for BPD.

Medications can be targeted to specific symptoms, i.e., short-term, low-dose antipsychotics for symptoms such as paranoid thinking, thought disorder or psychotic rage; antidepressants for symptoms of depression, etc. However, experienced clinicians know that pharmacotherapy must be adjunctive to both individual and group psychotherapy.

Unfortunately, borderline patients usually require extended psychotherapy which, in this era of HMO-driven limitations of benefits, can be difficult to sustain. Dialectical Behavior Therapy (DBT) is one method that has proven effective in helping patients with BPD. Since borderline patients generally do better with structure, this cognitive-behavioral treatment—when implemented by an experienced practitioner and for a sufficient time period—helps patients learn to live with and manage their illness.

It is important to realize that BPD is a very complex illness that is confounded by multiple symptoms and comorbidities. Therapists have reported difficulties and frustration in treating these patients, for whom rage (often vociferously expressed) is a central problem. Individuals with BPD should be referred to a physician qualified to diagnose and treat this disorder.

For more information about BPD, treatment, and professionals, contact The Treatment and Research Association for Personality Disorder (TARA) at 212-966-6514 or the National Alliance for the Mentally Ill (NAMI) at 800-950-6264.

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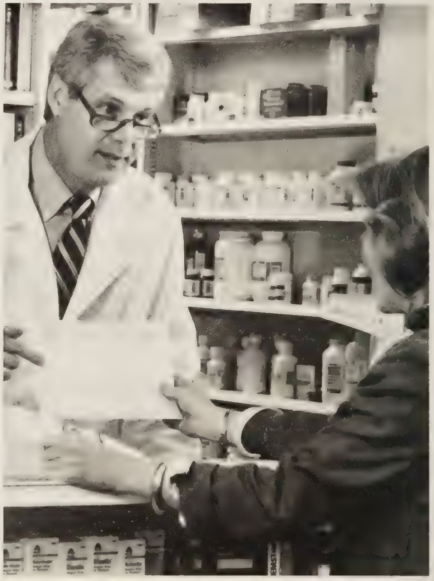

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Interactions...

School of Pharmacy Teams with PEAC to Promote Drug Free Learning Environment

Anthony Tommasello, Pharmacist, MS, School Associate Professor

In a move that puts the University of Maryland in the forefront on a serious issue affecting student life and professional health, the School of Pharmacy has teamed up with the Pharmacists` Education and Assistance Committee (PEAC). The School has approved new policies to promote drug free learning environments and to give troubled students confidential access to the services of PEAC. These new policies will 1) encourage the discovery and recovery of substance impaired or addicted pharmacy students, and 2) protect patients from potential harm caused by impaired students in all practice experiences. Under these policies, students pledge their dedication to provide excellent care in all pharmacy practice settings. In addition, all students will have access to PEAC services and will be granted the same protections afforded to pharmacists under a PEAC contract, including confidentiality.

The School of Pharmacy enjoys a long tradition of national leadership on matters of substance abuse prevention in the community, the development of curricular content on addiction diagnosis and treatment, and the creation of policies for dealing with the problem of drug impaired pharmacists. As far back as the 1960's, our pharmacy students were conducting drug education classes in middle schools throughout the state through the Student Committee on Drug Abuse Education (SCODAE). This program became a national model of community drug abuse education for pharmacy schools, under a grant from the federal Department of Education. SCODAE continues to be a training program for pharmacy students as well as an important community service program of the School.

The School of Pharmacy leads the nation in the academics of addiction. Substance Abuse material is built into the core curriculum of the School, and all pharmacy students are exposed to principles of diagnosis, referral, and treatment of drug abuse and addiction. In 1987, the School instituted the Office of Substance Abuse Studies (OSAS) dedicated to research, education, and service in the area of substance abuse and its treatment. Through OSAS, pharmacy students opt for clinical rotations in addictions treatment, participate in research projects, and submit papers on topics of drug abuse for publication in the *Pharm/Alert* newsletter.

The School of Pharmacy supported the creation and development of the Pharmacists' Rehabilitation Committee (now PEAC). The School helped with fund-raising activities in the early years of PEAC and continues to provide space to hold monthly meetings. Maryland was among the vanguard of states that developed a program of addressing the problems of substance abuse and dependence among pharmacists.

At the recent annual meeting of the American Association of Colleges of Pharmacy held in Boston, Maryland's leadership in the arena of substance abuse was apparent. The School's policies were presented by Robert Beardsley, Associate Dean for Student Affairs, and were the focus of discussion in the Special Interest Group on Substance Abuse. Our approach to partner with PEAC opens the door for students to the full range of supportive services that have been extended to practicing pharmacists for over 15 years. Analogous to the relationship between pharmacists and PEAC, students accessing PEAC services sign a contract with PEAC laying out the treatment expectations. By complying with the contract, students can complete their education without serious disruption and can launch their career free of the fetters of drug abuse and dependence.

As the new policies were being crafted and discussed among the faculty, consideration was given to the total academic environment. The external learning locations of professional experience in dispensing practice and clinical care as well as classroom settings were kept in mind. Faculty and administration were sensitive to the needs and expectations of Experiential Learning Program preceptors. The School will not place a student who is unfit for practice in any patient care or dispensing environment. These policies do not expose preceptors or the public to students who are considered to be unstable in their treatment program.

Drug dependence is an occupational hazard for health professionals. The combination of high job stress and easy drug availability conspire to increase the risks of chemical dependence among pharmacists. As our students move into the practice environment, they assume the role of the practitioner with all its rewards and its risks. Our policies are not only reasonable, but also necessary to fulfill the School's longstanding commitment to the profession to turn out graduates of the highest caliber.

For a copy of the policies, contact Associate Dean for Student Affairs Dr. Robert Beardsley. Email address: Rbeardsl@rx.umaryland.edu – Phone: 410-706-7587.

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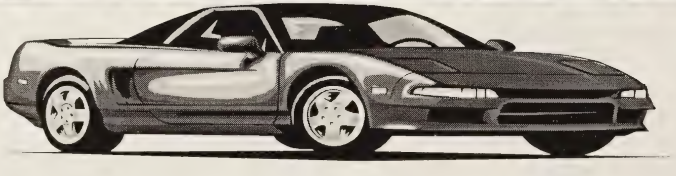

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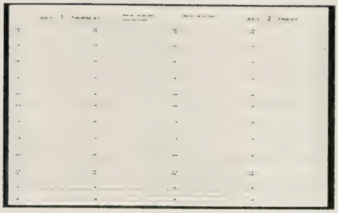

Improved Patient Compliance Through Drug Calendars

by
Neil V. Smith, Pharm.D. Candidate
University of Maryland Baltimore

Abstract. Improved patient compliance begins with enhanced patient care. Patient noncompliance to drug regimens and the barriers opposing compliance is discussed. Reasons for noncompliant behavior are multifactorial, complex and include the incorrect application of chronotherapeutics. Therefore, strategies for increased patient compliance are explored.

Computer technology provides the community retail pharmacy with an excellent opportunity to increase patient compliance. Drug education profiles complimented with computer generated drug calenders is introduced. Drug calendars can be given to every patient during each pharmacy visit free of charge. Patients are able to see at a glance what medications need to be taken at what time of the day. By taking medication at the recommended time of day (i.e., with meals, before meals, in AM, PM, or at bedtime) the therapeutic effects of each medication can be enhanced. Drug calenders are designed to increase patient compliance, thus enhancing the ability of the community retail pharmacy to provide improved patient care.

As the last health care professional the patient encounters, the pharmacist has the opportunity and specialized knowledge of drugs to encourage medication compliance. During a patient's drug therapy the pharmacist represents an important source of information to the patient. Despite current efforts to curb poor compliance to drug regimens, studies have shown a substantial population of partial and noncompliers.[1-5] Furthermore, research has identified that noncompliance has resulted in $1.5 billion in lost earnings annually, 20 million lost work days and an estimated $76 to $100 billion each year charged to American corporations and insurance companies.[6-7] Compliance has become such a large issue that the "National Council on Patient Information & Education...named noncompliance 'the nation's other drug problem'."[8]

Rationalities for this devastating problem of noncompliance are multifactorial and plentiful. They range from failure to have prescriptions filled to incorrect administration of medication and involve social, physical and mental barriers.[1,9-11] Multiple drug regimens and multi dosing therapy are often sited as a major barrier, particularly with the elderly.[1-3,9-10,12-13] New research is showing that part of the problem lies with the drug therapy and not the patient.[14-16] For example, a patient could be taking his/her medication properly as prescribed by his/her physician but may not be obtaining ideal therapeutic outcomes of his/her medication. This can be contributed to the patient taking his/her medication at the wrong time of day. Although this example is not the traditional compliance situation most thought of, it does illustrate the increasing importance of chronotherapeutics in drug controlled disease management and compliance. At present, chronotherapy is effectively used in the treatment of various disease states such asthma, hypertension, and cancer.[14-16] Unfortunately, most patients who could benefit from such regimens are taking their medications at the wrong time of day. Therefore, this needless medication error becomes another barrier to drug regimen compliance.

Overcoming the formidable barriers of noncompliance is no easy task. Indeed, solutions for better compliance are often complex, demanding and require the aid of a collaboration of health care professionals. In theory, an educated patient is a compliant patient. Patient education may include one or more of the following: verbal communication or counseling, written communication, medication calendars, special medication containers, compliance packaging, self-monitoring, health care professional monitoring, mailed reminders, computer generated leaflets, or voice-activated reminders.[6,9] Moreover, successful education requires three characteristics. As described by Rudd, these characteristics are: first, individualized and personalized maneuvers with active patient participation; second, multifactorial components rather than one intervention; and third, continual reinforcement.[1] In meeting these criteria, the retail pharmacist has the unique opportunity to complete the health care team by providing much of the needed patient education.

Does improving patient compliance require the retail pharmacist to drastically alter the work environment, spend more time counseling patients, or create a larger work load?

By looking at what is already working in the retail pharmacy, evidence shows that improvement may not necessarily require such drastic changes. The U.S. Food and Drug Administration recently reported the results of a survey showing what percentage of patients received written information about their prescription drugs. From 1982 to 1994 the percentage of patients that received written drug information from their pharmacy increased nearly 3½ fold, from 16% to 55%.[17] Much of the increase was due to the use of computer generated drug information. Computers can provide the retail pharmacist a versatile alternative to drastic change.

Examples of computer supplied information for patients are increasing in number each day. Thomas J. Thornton, a consultant pharmacist entrepreneur in Traverse City, Michigan recently started Pharmnet Therapy Monitoring Service. Pharmnet is a new company that offers patients a computerized phone call up to six times a day as a reminder to take medication.[18] In a similar effort, Dr. David Sclar of the University of Southern California showed that with the use of computerized voice reminders patient compliance increased from 53% to 79%.[6] According to Dr. Sclars' results, computer patient monitoring seems to be an ideal direction for retail pharmacy. However, the cost of computerized patient monitoring creates a different picture. In the case of Pharmnet, the patient may pay up to $480 per year for the offered services.[18] Certainly computers can offer an equally efficacious program for a much smaller cost.

In 1981, Jackson and Edwards published a report detailing the use of a medication card in both retail and hospital pharmacies.[12] A medication card, or drug calender, offers the patient a specialized time schedule for drug administration. It further enhances the patient's knowledge on when to take and when not to take his/her medication. Jackson and Edwards concluded that the drug calendar was a successful intervention for improving compliance; however, its practicality in the retail setting was erroneously underestimated.[12] Since this report, numerous additional accounts of drug regimen calendars have been reported as good solutions to compliance, yet little is known of their use in the retail pharmacy.[3-4,9,19] With the advancement in computers and computer software, providing each patient with a personalized drug calender is a realistic concept possible in today's retail pharmacy.

Retail pharmacies can improve patient compliance by providing each patient with a personalized drug calender. As an appendage to patient drug education already offered by most retail pharmacies, a drug calender can serve as a simple solution for people confused with their medication regimens. A single sheet of paper generated and printed by the pharmacy computer, the drug calender can inform each patient of optimal and specific times to take each medication. Moreover, this service can be offered to every patient free of charge.

Implementation of drug calenders can increase retail pharmacy revenues. By increasing patient compliance, the drug calender will also increase the renewal rate of prescriptions by the patient. Jackson and Huffman reported on the potential increase in pharmacy revenues associated with increased refill compliance to be in the tens of thousands.[6] Therefore, the cost of implementing a drug calender program will more than pay for itself as refill compliance increases.

Expanding retail pharmacy to incorporate drug calenders will enhance patient care by improving compliance. Many patients find themselves trying to understand when they should take their drugs. For example, an AIDS patient frequently ends up "taking anywhere from 10 to 15 or even more medications at various times during the day and night."[20] Furthermore, elderly patients over the age of 65 take on the average four or more prescriptions and consume approximately 30% of all prescription medication.[2-3,8,13] "Some patients have little understanding or insight as to why they need to take so many different 'pills' each and every day for the rest of their lives."[21] Therefore, to better help patients understand when and why they need to take their medication is of a high importance to the pharmacist. Drug calenders can aid in this endeavor.

Drug calenders are simple and easy to understand, but they do require explanation.[19] The pharmacist might be leery about how much time commitment drug calenders will require. However, this shouldn't be a concern. With video technology, patients can learn about the new service provided by the retail pharmacy while waiting for their prescriptions. In this manner, minimal time is required from the pharmacist to explain the use of the drug calender. Furthermore, the responsibility of the pharmacist to ensure patient understanding of their medication regimen is upheld.[6]

Drug calenders actually work to improve compliance.[3,9,12,19] Improving compliance, as described by Rudd's three characteristics, requires the stratagem to be individualized, multifactorial, and reinforced.[1] Drug calenders can be offered in a retail pharmacy to everyone free of charge. Drug calenders supplement patient drug information already offered by most retail pharmacies. And finally, drug calenders can be given to the patient each time a prescription is filled at the retail pharmacy. Going beyond Rudd's criteria, drug calenders have the unique ability to combine the latest technology and research into an understandable presentation for each patient.

In summary, patient compliance costs the U.S. billions of dollars each year.[6-7] Multiple rationalities and barriers exist in connection with poor compliance. Solutions for the problem are multifactorial and often complex. Rudd stated that all solutions must be individualized, combine multiple components, and be reinforced.[1] The retail pharmacy must accept change and implement new technology to enhance patient compliance. Drug calenders provide a cost effective, easy to implement opportunity for the retail pharmacy to improve patient compliance. Furthermore, drug calenders meet Rudd's criteria and provide an excellent method to enhance patient care. The future is now. Therefore, retail pharmacy must change to include improved patient services such as drug calenders.

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A Survival Kit for Everyday Living

Items needed: Toothpick, Rubber Band, Band-Aid, Pencil, Eraser, Chewing Gum, Mint, Candy Kiss, and Tea Bag

Why, you say?

1. ***Toothpick***: to remind you to pick out the good qualities in others.

2. ***Rubber Band***: to remind you to be flexible. Things might not always go the way you want, but it will work out.

3. ***Band-Aid***: to remind you to heal hurt feelings, yours or someone else's.

4. ***Pencil***: to remind you to list your blessings every day.

5. ***Eraser***: to remind you that everyone makes mistakes and it's OK.

6. ***Chewing Gum***: to remind you to stick with it and you can accomplish anything.

7. ***Mint***: to remind you that you are worth a mint.

8. ***Candy Kiss***: to remind you that everyone needs a kiss or a hug every day.

9. ***Tea Bag***: to remind you to relax daily and go over that list of blessings.

Adapted from St. Agnes News

You Decide...

As we look back it is not hard to see why disease was prevalent and nutrition so poor. We certainly have come a long way. So, you think you have it so bad...

Anne Hathaway was the wife of William Shakespeare. She married at the age of 26. This was really unusual for the time.

Most people married young, about the age of 11 or 12. Life was not as romantic as we may picture it. Here are some examples: Anne Hathaway's home was a 3 bedroom house with a small parlor, which was seldom used (only for company), kitchen, and no bathroom.

Mother and Father shared a bedroom. Anne had a queen sized bed, but did not sleep alone. She also had two other sisters and they shared the bed also with 6 servant girls (this was before she married). They didn't sleep like we do lengthwise but all laid on the bed crosswise. At least they had a bed. The other bedroom was shared by her 6 brothers and 30 field workers. They didn't have a bed. Everyone just wrapped up in their blanket and slept on the floor. They had no indoor heating so all the extra bodies kept them warm.

They were also small people, the men only grew to be about 5'6" and the women were 4'8". Amazing to think that in their house they had 27 people living there.

Most people got married in June. Why? They took their yearly bath in May, so that they were still smelling pretty good by June. In case they were starting to smell, June brides would carry a bouquet of flowers to hide their body odor. Like I said, they took their yearly bath in May, but it was just a big tub that they would fill with hot water. The man of the house would get the privilege of the nice clean water. Then all the other sons and men, followed by the women and the children. Babies were always last to get a bath. By then the water was very thick. Thus, the saying, "don't throw the baby out with the bath water." It was so dirty you could actually loose someone in it.

I'll describe their houses a little. You've heard of thatch roofs? Well, that's all they were. Thick straw, piled high, with no wood underneath. They were the only place for the little animals to get warm. So all the pets; dogs, cats and other small animals, mice, rats, bugs, all lived in the roof. When it rained it often became slippery. Sometimes the animals would slip and fall off of the roof. Thus the saying, "it's raining cats and dogs."

Since there was nothing to stop things from falling into the house they would just try to clean up a lot. But this posed a real problem in the bedroom where bugs and other droppings from animals could really mess up your nice clean bed. They found that if they would make their beds with big posts and hang a sheet over the top, then it would prevent that problem. That's where those beautiful big four poster beds with canopies came from.

When you came into the house you would notice most times that the floor was dirt. Only the wealthy had something other than dirt. Hence, we now have the saying "dirt poor." The wealthy would have slate floors. That was fine but in the winter they would get slippery when they got wet. So they started to spread thresh on the floor to help keep their footing. As the winter wore on they would just keep adding more and more thresh until when you opened the door it would all start slipping outside. So they put a piece of wood at the entry way, a "thresh hold."

In the kitchen they would cook over the fire. They often had a fireplace in the kitchen/parlor, but that was seldom used. Sometimes a fireplace was located in the master bedroom. They had a big kettle that always hung over the fire. Every day they would light the fire and start adding things to the pot. Mostly the kettle contained vegetables, because they couldn't get much meat. They would eat the stew for dinner, then leave the leftovers in the pot to get cold overnight only to start it all over the next day. Sometimes the stew would have food in it that had been in the kettle for a whole month! Thus the rhyme: peas porridge hot, peas porridge cold, peas porridge in the pot nine days old."

Sometimes they managed to procure some pork. They really felt special when that happened. When company came over they even had a rack in the parlor where they would bring out the bacon and hang it to show it off. That was a sign of wealth and that a man "could really bring home the bacon." They would cut off a little to share with the guests and they would all sit around and "chew the fat."

If you had money your plates were made out of pewter. However, some of their food had a high acid content causing some of the lead to leach out into the food. It was noticed that tomatoes seemed to cause this more than other foods. So they stopped eating tomatoes, for 400 years. Most people didn't have pewter plates though. They all had trenchers. A trencher was a piece of wood with the middle scooped out like a bowl. They never washed their boards and at times worms would get into the wood. After eating off a trencher which contained worms they would get "trench mouth." For this reason, if you were traveling and wanted to stay at an Inn, the Inn usually provided the bed but not the board.

The bread was divided according to status. The workers would get the burnt bottom of the loaf, the family would get the middle and guests would get the top, or the "upper crust."

They also used lead cups for when they would drink their ale or whiskey. The combination would sometimes knock them out for a couple of days. It was not therefore uncommon to be walking along the road and here would be someone knocked out and mistaken for dead. They would pick the corps up and take it home to make it ready for burial. They began to realize that if they were slow about it, the person would often wake up. Furthermore, possibly not all of the people they were burying were actually dead. So they would lay the corps out on the kitchen table for a couple of days just to make sure the person was dead. In the meantime, the family would gather around, eat, drink and wait to see if the person would wake up. That's where the custom of holding a "wake" came from.

Since England is so old and small they started running out of places to bury people. So they began digging up coffins, taking the bones to a house and re-using the graves. As they opened these coffins, they found some had scratch marks on the inside. It was quickly noticed that 1 out of 25 coffins were contained scratches on the inside. This helped with the realization that they had still been burying people alive. So they tied a string on the corps' wrist and lead it through the coffin, up through the ground and tied the other end to a bell. Someone would have to sit out in the graveyard all night listening for the bell. That is how the saying "graveyard shift" was made. If the bell rang, they would know that someone was "saved by the bell" otherwise he was a "dead ringer."

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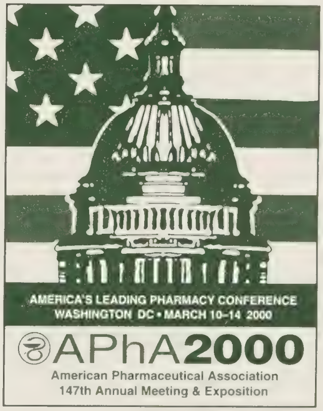
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Continuing Education for Pharmacists

Volume XVI, No. 7

Patient Counseling: Skin Cancers; Part 1

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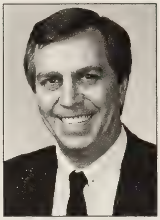
Goals. The goals of this lesson are to discuss skin cancers, and present information useful in counseling patients on management of these conditions.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. differentiate between pathologic characteristics of various skin cancers;
2. choose from a list those components that distinguish one form of skin cancer from another;
3. exhibit knowledge of means to reduce the incidence of skin cancers and drug therapy for treating them;
4. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to reduce the incidence of skin cancers and/or treat them; and,
5. demonstrate knowledge on counseling patients on how best to prevent and treat skin cancers.

Gossel



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Skin cancers are the most common neoplasms of humans. Skin cancers have been called a disease of old age. About one-half of all Americans aged 65 years will reportedly have experienced at least one skin cancer during their lifetime. At the same time, the prognosis is excellent if detected early.

This first lesson in the two-part series focuses on the three most common skin cancers: basal cell carcinoma, squamous cell carcinoma, and malignant melanoma. It describes their etiologies and characteristics, and discusses how to protect against and treat them.

Nonmelanoma Skin Cancers

This year, approximately 900,000 new cases of nonmelanoma skin cancers, i.e., basal cell carcinoma and squamous cell carcinoma, will be diagnosed in the U.S. These two forms of cancer account for approximately one-half of all malignancies in the U.S., and about 1.7 percent of all cancer-related deaths.

The average age of onset for both of these cancers is 60 years. They are rare in persons under 40 years of age. Exceptions include tumors which may occur in younger individuals who have an hereditary disorder such as xeroderma pigmentosum. The incidence of basal and squamous cell carcinomas in Caucasians is greater than in non-white populations.

There is overwhelming evidence that ultraviolet (UV) radiation emanating from the sun is a major determinant of incidence. This is especially significant for UVB at wavelengths of 290-320 nm. For persons living in the U.S., the incidence in Caucasians increases 15 percent for each degree of latitude south. Chronic exposure to UV radiation from sunlight is the cause of more than 90 percent of all skin cancers. Males contract basal cell and squamous cell carcinomas about twice as often as females.

After quantity of sunlight, the next most frequent cause of skin cancer that affects development of both carcinomas in all populations is the amount of skin pigmentation. For example, northern European populations with blue eyes, light hair and skin, and freckles are at highest risk for developing all types of skin cancers.

The majority of skin cancers form on surfaces that receive the most sun. This includes the forehead, eyelid margins, upper cheeks, neck, skin folds around the nose and lips, and hands. Areas of high concentration of hair follicles are also good candidates for basal cell carcinoma development.

Other risk factors include

chronic exposure to arsenic, cytotoxic drugs (topical and systemic), and coal tar. Irradiation of benign tumors is a risk factor. Other factors that destroy the skin's cells, such as inflammation, scarring following serious burns, chronic ulcers, and tattoos are believed to contribute to the development of carcinomas.

Basal Cell Carcinoma

Arising from the basal cells of the epidermis, basal cell carcinoma is the most common skin cancer of humans accounting for three out of four of all malignant skin tumors. While most tumors occur mainly in sun-exposed areas, about one-third appear in areas of limited sun exposure.

There are four main forms of basal cell carcinomas. **Nodular** tumors, the most common, usually appear as a single lesion on the face. They are small papules (circumscribed, solid elevations of the skin) with a pearly, translucent border. These tumors may range in color from flesh tones to slightly reddish. Redness appears from dilated capillaries and arteries within the papule. There is usually no inflammation in the skin surrounding the lesion.

These tumors develop more slowly than squamous cell carcinoma. At some point, the center of the spreading lesion collapses leaving a raised, firm border. Underlying tissues may then become involved. Untreated lesions ulcerate in time because the tumor cells do not contain sufficient amounts of the structural protein keratin. Basal cell carcinoma may result in severely deforming ulcerations on the face and trunk if they are treated inadequately.

The second form of these lesions is termed **superficial** basal cell carcinoma. These occur in multiples on the trunk, especially on the back and chest. Each lesion is oval to irregular. It will appear lightly pigmented to red in color, and show a sharply demarcated and slightly elevated thread-like border. The surface will usually appear as scaling with areas of healing and scar formation in the central portions. The lesions may mimic eczema or psoriasis in appearance.

Pigmented basal cell carcinoma appears as a blue-black nodule or plaque. It will have a pearly, opalescent sheen. Though melanocytes are stimulated to produce more pigment, they are not involved histologically in the tumorigenic process and, thus, do not worsen the prognosis.

Sclerosing (scarring) basal cell carcinoma is the fourth form. Yellowish-white, waxy, and hardened (sclerotic) lesions, they have no distinct border. Lesions occur on the face, head, and neck, and are the most difficult to recognize clinically. They are often mistaken for a scar or enlarged pore. As they spread slowly across the area, a central core of sclerosis appears.

The major risk with basal cell carcinomas is that they may develop into an invasive tumor, a process that can occur over 10 to 20 years. Once they invade subcutaneous tissue, they can cause extensive damage to cartilage, bone, and nerve structures. This, in turn, can lead to disfigurement. Death can occur in this advanced stage. Metastasis to distant sites is rare.

Squamous Cell Carcinoma. A malignant cancer of the epidermal cells that produce keratin (keratinocytes), squamous cell carcinoma is less common, but more aggressive than basal cell carcinoma. This form of cancer is locally invasive, but it has the potential to metastasize.

Squamous cell carcinoma most often develops in areas exposed to the sun, its incidence increasing the closer one lives to the equator. Tumors appear typically on the upper face and lower lip, ears, and back of the hands. The surrounding skin frequently shows evidence of earlier sun-induced damage. Squamous cell carcinomas may occur at any site on the skin and mucous membranes including the anus, vulva, and penis.

While more common than basal cell carcinomas in Blacks, its incidence is still low in all populations combined. However, it is reported that the true incidence of squamous cell carcinoma may be higher than published figures show, because many practitioners remove and treat this form of cancer without reporting it to the appropriate cancer registry.

A squamous cell carcinoma usually appears as a hardened lesion surrounded by inflammation in skin that has been damaged previously. It may look like a basal cell carcinoma at first glance, except that a squamous cell carcinoma grows much more quickly and is usually firmer, with greater hardening and inflammation.

When the tumor appears on normal skin, it develops as a single, slowly developing nodule with a hardened base. It will be firm to the touch and in time form a central crust with eventual ulceration.

Treatment of Basal Cell and Squamous Cell Carcinomas

The prognosis with proper treatment for basal and squamous cell carcinomas is very good. Lesions that appear on normal skin are usually more aggressive than those which occur on sun-damaged skin. Recurrent lesions are more difficult to treat, regardless of cause.

Prevention and early detection must be stressed even though most skin cancers have a low mortality rate. This will help assure that patients have minimal disfiguring and reduce the cost of therapy.

Small basal cell or squamous cell carcinomas, less than 1 cm in diameter, can be treated by removing the tumor surgically. Chemosurgery may be used when there is a chance of causing cosmetic disfigurement. This procedure involves removing the upper portions of the tumor surgically, followed by treatment of the underlying areas with zinc chloride paste which fixes (precipitates) the protein of the tissue. Thin tissue slices are removed and examined microscopically. Malignant cells are treated repeatedly until there is no further evidence of the tumor. Though curative, this procedure is time consuming and expensive. It is recommended when tumors recur within a scarred area and where surgical removal alone is not reliable, for sclerosing basal cell carcinoma, and for lesions where saving tissue is essential, such as those on the face or fingertips.

Fluorouracil. Fluorouracil, 15 to 20 percent, is useful for treating superficial basal cell and squamous cell carcinomas. Since non-chemotherapeutic treatment is effective in localized single lesions, it is usually reserved for patients with multiple or widespread lesions. Tumors that are deeply invasive should not be treated with fluorouracil because the drug does not penetrate the skin beyond a few millimeters.

Fluorouracil should be applied evenly with care taken to avoid accumulating excessive amounts of drug product in any specific area of the skin. Patients should wash their hands thoroughly before and after administration.

Within three to seven days after initiating treatment, the skin will redden and progress to tenderness, scaling and erosion. This is the signal to cease application. The reaction subsides quickly, and lesions on the face heal within two to six weeks. Healing of lesions on the arms requires additional time. Fluorouracil treatment courses may be repeated. Topical steroids can be applied to areas of intensive irritation.

Fluorouracil exerts anti-tumor action through a cytotoxic mechanism, rather than nonspecific inflammatory sloughing of superficial skin layers. Sloughing of skin that occurs may be due to a local delayed hypersensitivity reaction.

Radiation. On sensitive areas such as the eyelids, ear, lips or nose, radiation therapy is particularly useful. Irradiation eliminates the need for skin grafting necessitated by surgery. Cosmetic results are generally good to excellent. Irradiation should be limited to older individuals because of the risk of radiation-induced tumors 20 or 30 years later.

Cryosurgery using liquid nitrogen to freeze the tumor is useful on areas such as the face that are cosmetically sensitive, in patients who refuse surgery, or where there is abundant scar tissue. It is also used in cases which would render surgical excision difficult or dangerous.

Carbon dioxide laser treatment may help manage selected tumors. It is especially useful in patients who have a predisposition to bleeding since bleeding rarely occurs when this therapy is used.

Interferon alfa has been suggested as a logical means to treat nonmalignant skin carcinomas. Studies are underway to assess its potential value.

Malignant Melanoma

Representing only one to three percent of all cancers in the U.S., malignant melanoma is the least common form of skin cancer. It is also the most potentially devasting form. Its incidence is on the rise. It is estimated that there will be approximately 41,600 new cases of melanoma reported in the U.S. during 1998, with 7,300 deaths. The incidence has increased nearly 80 percent between 1973 and 1987 at a rate approximately four percent per year. The alarmingly high rate is expected to continue unless preventative measures are adopted. By the year 2000, one in every 90 Americans is expected to develop melanoma during his or her lifetime.

Rare in young children, the incidence begins to increase in the late teenage years and continues until the age of 65 to 70 years. After that it decreases. The incidence in Caucasians is six to seven times higher than in African-Americans. Melanoma affects males and females nearly equally. When treated appropriately, women tend to have a higher survival rate.

Table 1
A-B-C-D Rule Useful in Determining Melanoma

- *A = Asymmetry.* The lesion is asymmetric due to irregular, random growth of the malignant cells along with an irregular surface and nodules and papules.
- *B = Border Irregularity.* The lesion's edges are notched or blurred caused by pigment spreading out beyond the borders.
- *C = Color.* Lesion pigmentation is not uniform. Shades of tan, brown, and black are often noted within the same lesion; red, white and blue hues may be noted.
- *D = Diameter.* The lesion diameter is greater than 6 mm before it is recognized.

Excessive exposure to UV radiation of sunlight is a causative factor in melanoma. As with other sun-related skin cancers, the incidence increases with proximity to the equator. Individuals with light skin and light-colored eyes, and who sunburn easily are at greatest risk. Persons who have been sunburned severely, especially during childhood or adolescence, are at special risk. At high risk are individuals who work indoors and then spend most leisure time outdoors. Persons with a family history of melanoma are four times more likely to develop it than individuals without such a history.

Another high-risk group is composed of individuals who had a higher than average number of moles (melanocytic nevi) as children. Infants who are born with moles of this type (20 cm or more in diameter) are at increased risk of developing melanoma.

Melanoma differs from basal cell and squamous cell carcinomas in that it also develops in areas of the body that are not exposed to the sun. Melanoma appears on the head and neck less than 25 percent of the time in contrast to basal cell and squamous cell tumors which occur predominantly in those areas. Melanoma which appears in nevi is more likely to occur in areas not exposed to the sun.

Previously, it was assumed that dark-skinned persons would not develop melanoma. Skin pigmentation contains a rich component of melanin, an effective filter of UV radiation. Melanin scatters radiation to reduce its harm and absorbs the energy emitted from UV radiation. Because it is readily oxidized, it can help block chemical reactions leading to carcinogenesis. More recent evidence suggests that even persons who are heavily pigmented develop melanoma.

Pigmented skin that may be malignant often appears different from normal skin. The American Cancer Society provides its "A-B-C-D Rule" to help distinguish the characteristics of malignant lesions (Table 1).

Additional features that suggest melanoma include the following changes in:

- *surface*: e.g., oozing, bleeding, crusting, ulceration, scaliness;
- *sensation*: itching, tenderness, or pain;
- *elevation*: a sudden elevation of a previously flat area;
- *consistency*: especially lesions that soften or crumble easily; and,
- *surrounding tissue*: especially when the skin in the surrounding area begins to redden, swell, and become pigmented.

Unlike the lesser invasive basal cell and squamous cell carcinomas, melanoma spreads quickly throughout the body and is a major cause of cancer-related death.

It is imperative that melanoma be diagnosed early. There is a specific point in melanoma development, after which survival is poor. For example, survival is more likely if the malignant lesion is less than 0.76 mm thick. The thinner the lesion, and the more quickly it can be removed surgically, the better is the patient's chance for complete cure.

Treatment of Melanoma. The only proven curative therapy is surgical resection. This requires excision of the primary site and an additional 2.5 to 5 cm area of normal tissue around the lesion. Lymph nodes in the surrounding area will be removed if enlarged and tumor cells are present. Once the disease has invaded the regional nodes, treatment will be largely ineffective.

Hormonal therapy, radiation and hyperthermia have been attempted without improving the response rate significantly. Immunotherapy still remains of interest to oncologists treating melanoma. Melanoma cells express tumor-associated antigens, and the host's response to these antigens can be demonstrated and studied serologically.

Fortunately for some patients, melanoma lesions may regress without therapy. However, patients should be counseled to obtain treatment and not rely on spontaneous regression.

Prevention and Early Detection of Skin Cancers

The most effective means to prevent skin cancers is to limit exposure to sunlight and tanning booths. Chronic exposure to damaging UV radiation, and the number of sunburn events experienced early in life are primary risk factors for development of skin cancers. By age 20, most individuals will have received 80 percent of their lifetime sun exposure. Persons in high-risk groups (i.e., light-skinned, blue-eyed, blonde- or red-haired people; those who freckle or burn rather than tan) should be especially proactive in limiting their sun exposure. A personal or family history of skin cancer should sharpen one's awareness to the likelihood of cancer. Individuals with a family history, particularly, should take special measures to avoid excessive exposure to sunlight (Table 2).

Table 2
High Risk Factors for Skin Cancer

- sunburn easily, fair skin, blonde or red hair
- outdoor work or exposure to excessive sunlight
- multiple melanocytic nevi (moles)
- family history of skin cancer
- severe sunburns during childhood or adolescence
- genetic disease of intolerance to sunlight
- residence in the South or Southwest where solar intensity is greatest

Sunscreens should be applied to all sun-exposed areas of the body, even if exposure is limited to short periods. The FDA classifies sunscreens as drugs intended to protect the structure and function of the human skin against damage from UV radiation.

Mortality from skin cancers can be reduced. Patients should learn to recognize the features of a pigmented lesion that appears suspicious and seek treatment.

Summary

Part 2 of this two-part lesson series describes the correct use of sun-protection agents. It also includes information on counseling patients on the proper application and use of these products.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Skin Cancers; Part 1." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 07/15/01. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-98-007-H01.

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1. All of the following are true EXCEPT:
   a. skin cancers are the most common neoplasms.
   b. approximately one-half of all Americans aged 65 years or older will have experienced at least one skin cancer during their lifetime.
   c. the prognosis for skin cancer is excellent if it is detected and treated early.
   d. the average age of onset for skin cancer is 35.

2. The major determinant for developing skin cancer is:
   a. asbestos. c. ultraviolet light.
   b. heredity. d. viruses.

3. The most common form of skin cancer is:
   a. basal cell carcinoma.
   b. malignant melanoma.
   c. squamous cell carcinoma.
   d. malignant lymphoma.

4. The most common form of basal cell carcinoma is:
   a. sclerosing. c. superficial.
   b. nodular. d. pigmented.

5. The form of skin cancer referred to in question #4 appears as:
   a. multiple lesions mimicing eczema or psoriasis.
   b. blue-black plaques with an opalescent sheen.
   c. single, solid elevations of the skin with a pearly, translucent border.
   d. yellowish-white, waxy and hardened lesions with an irregular border.

6. The form of skin cancer that is most likely to affect the epidermal cells that produce keratin is:
   a. basal cell carcinoma.
   b. malignant melanoma.
   c. squamous cell carcinoma.
   d. malignant lymphoma.

7. The chemotherapeutic agent used to treat superficial basal cell and squamous cell carcinomas is:
   a. cyclosporine. c. interleukin.
   b. fluorouracil. d. methotrexate.

8. Patients using the product referred to in question #7 should be counseled to do all of the following EXCEPT:
   a. apply an occlusive bandage.
   b. apply the product evenly to the lesion.
   c. avoid accumulation of excessive amounts on any specific area outside the lesion.
   d. wash their hands thoroughly before and after applying the product.

9. The American Cancer Society's "A-B-C-D Rule" to distinguish characteristics of malignant tumors refers to all of the following EXCEPT:
   a. asymmetry due to irregular, random growth of malignant cells.
   b. border irregularity caused by pigment spreading beyond the borders of the lesions.
   c. color due to the different shades of colors noted on the lesions.
   d. distance from the equator where the individual is exposed to sunlight.

10. If it is noted and treated early, the best therapy for malignant melanoma is:
   a. hormonal chemotherapy.
   b. full-body radiation therapy.
   c. cryotherapy with liquid nitrogen.
   d. surgical removal of the lesion.

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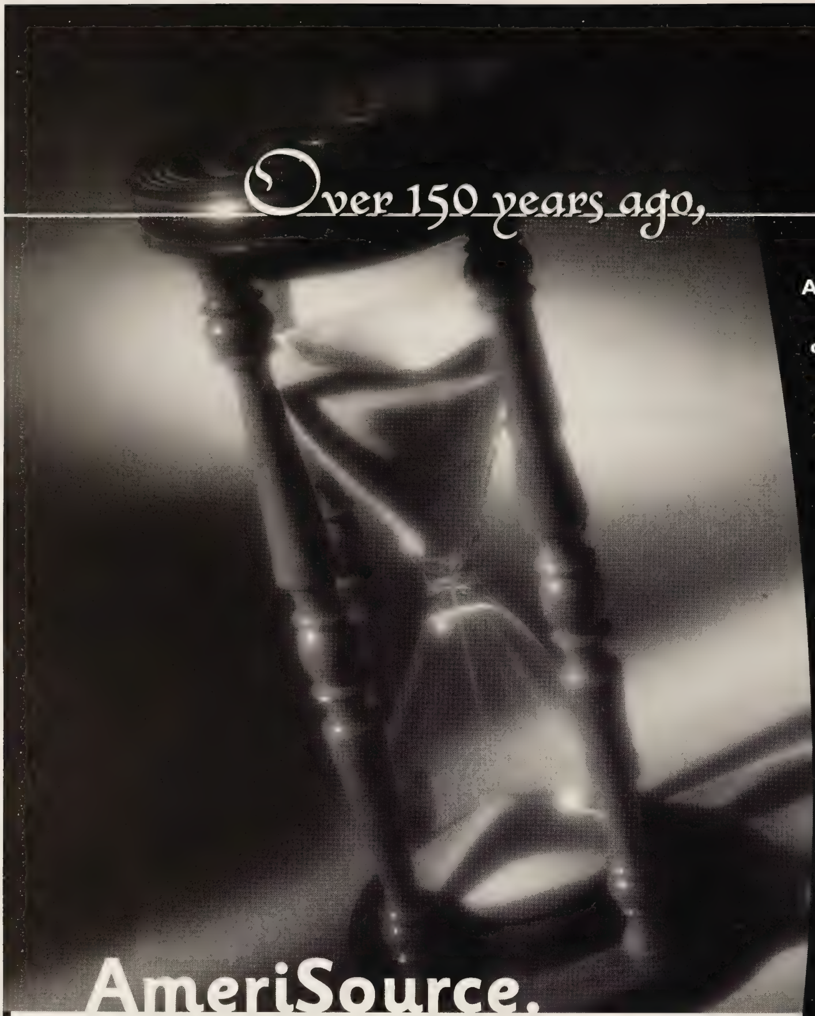

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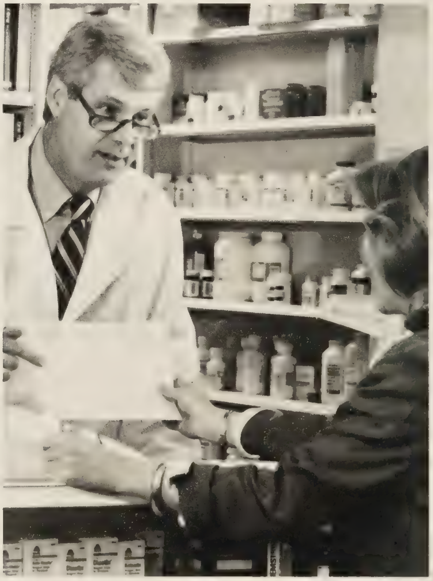

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President's Commentary

Working Together

Joseph A. DeMino, P.D.

For the first time, the three major pharmacy organizations have put their thoughts and plans together to advance community pharmacy in delivering quality health care in the 21st century. This is the first step toward positive actions to improve pharmacy practice and the delivery of pharmacy care to the patient. In a collective voice for community pharmacy, they have written and published a white paper entitled, "*Implementing Effective Change in Meeting the Demands of Community Pharmacy in the United States*." It was co-written by NACDS, APhA, and NCPA. This is a major step forward for the profession.

The document looks at the future of community pharmacy based on the realities of today and the expectations for tomorrow. It stresses the dual role of pharmacists in the safe and accurate dispensing of medications as well as patient care. Some say the pharmacist's role has been "redefined" from medication dispenser to patient care provider. It is more accurate to say the role of the pharmacist has been expanded.

The document also deals with the pharmacist shortage and how we can appeal to new pharmacy graduates. Many graduates are seeking alternatives to traditional practice. Many are frustrated and burdened with unproductive and time-consuming clerical tasks. Current pharmacy school graduates are often inadequately prepared for the realities of today's drug distribution systems. It is critical for our pharmacy schools to recognize the differences between institutional and community-based pharmacy practices, and better prepare the future pharmacists to qualify for both of these important roles.

With prescription drug use at an all-time high, 3 billion prescriptions filled this year and expected to reach 4 billion by the year 2005, we must focus on the challenges the profession faces in the delivery of quality service. Faced with the increased consumer demand for prescriptions we must utilize the new and improved tools and resources to maintain a safe and accurate drug distribution system. Two key areas to focus on are the appropriate use of technicians and the use of enhanced technology. We must continue to work with state boards of pharmacy to eliminate restrictions and rewrite laws and regulations. Automation can increase productivity and reduce error. It is important that regulations be modified so pharmacists can take full advantage of the safety and efficiency of electronic technology.

The use of a standard third-party benefit card is vital to avoid the clerical overload now experienced in many community pharmacies. It is time we start setting the standards for our profession.

Predicting the future is always difficult but certain truisms are evident. We all agree that there will be more prescriptions for more people, and to accomplish this more technology is needed. Adverse drug events are estimated to cost $100 billion this year. This is where pharmaceutical care should have its greatest impact. The state board recently had a presentation on strategies to improve patient safety related to medication errors. Studies show that pharmacists' efforts to enhance compliance and education about the drug regime result in improved health care.→

A great deal of work must be done to unite the profession with common goals to best meet the needs of the public. All facets of pharmacy must work together to advance community pharmacy in delivering quality health care in the 21st century.

We welcome the joint effort of NACDS, APhA, and NCPA.

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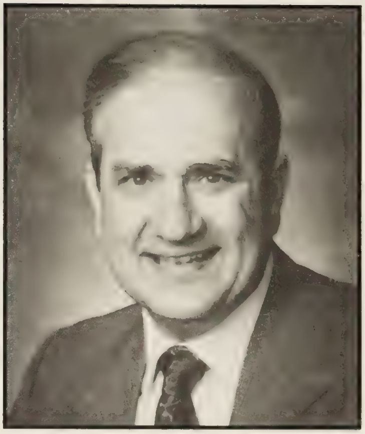
Frosty the Snowman	52%
The Grinch Who Stole Christmas	48%
A Charlie Brown Christmas	44%
Santa Clause is Coming to Town	40%

Source: Maritz AmeriPoll

Director's Column

MPhA—The Logical Place to Start

Howard R. Schiff, P.D.
Executive Director



With the explosion in number of prescriptions along with the graying of the Baby Boomers and the real possibility of Medicare prescriptions, the prediction of four billion prescriptions by 2004 (up from nearly three billion in 1999) may be an under-estimation.

- The number of pharmacists graduating from the school of pharmacy will not keep pace. Pharmacy education has changed to make us more people oriented and trained in pharmaceutical care, and we don't have the time to perform it. We will need technicians and robotics just to keep pace with the dispensing function.
- The cost of health care prescription coverage continues to rise; managed care reimbursements stink and there is no reason to think that they will improve.
- Workloads over just the past couple years have increased exponentially. There is already a shortage of pharmacists; and many of us "burn out" quickly.

What can we do about it? Certainly wringing our hands and crying will get us nowhere. We can, however, band together to ensure that we have a *voice* in the future of our profession. The MPhA is a logical place to start. If this association did not exist, it would have to be created to represent pharmacists in Maryland.

Your opinions and ideas are welcome. We want the idealism and zeal of the young as well as the experience of the not-so-young. You don't even have to be a "worker." We need everyone; those who want to be activists today; those who think they might be activists tomorrow; those who are too busy with work and family to be activists; and those who just want to sit and cheer or jeer those who are activists.

Remember, the MPhA represents the profession in Maryland. If you want your *voice* to be heard, take the all-important step to renew your membership.

On pages 19 and 20 you will find a summary of the many benefits of membership. Clip it out and save it. MPhA will continue to seek opportunities which allow members only discounts and benefits for our members.

Memberships will expire the end of December. Renewal notices have been sent. For your convenience a membership form is enclosed in this issue of the *Maryland Pharmacist*. Please don't delay—renew your MPhA membership today. If you have already renewed, please pass the membership form along to a friend or colleague. When a non-member joins MPhA you will receive a 10% discount on your 2001 dues. Get ten—and your 2001 dues are free!

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Vaccine Side Effects

Separating Mirage from Reality

by John D. Grabenstein, MS, Pharm

Question: *My patients are asking me about vaccine side effects they heard about on television or in the newspaper. What should I tell them?*

Vaccines recently have been the focus of unusually pointed criticism. It is easy to accuse a medication of causing harm. But a methodical review of available data shows that current vaccine recommendations are appropriate. Indeed, abstaining from vaccination is a more risky course of action. Modern vaccines are extraordinarily safe and reliable, offering some of the best value of our pharmacopeia.

Vaccines recently have been accused of causing multiple sclerosis, inflammatory bowel syndrome, autism, diabetes, and other serious conditions. While critics can paint compelling stories of how someone's life went bad shortly after a vaccination, objective analyses rarely show any elevated risk of harm resulting from vaccination. When tens of millions of people get vaccinated, random bad events will often be temporally associated with vaccination, by chance alone. Vaccinations are memorable events and are easily blamed when trying to explain inexplicable illnesses.[1-4]

Then how do we separate mirage from reality? How do we know if we are observing a coincidence or if a vaccine is causing harm? The answer is found by measuring whether the risk in the vaccinated group is significantly greater than that among the unvaccinated group.

Special teams of epidemiologists at the Centers for Disease Control and Prevention (CDC) and at the Food and Drug Administration (FDA) meet weekly to monitor vaccine safety. Each question of vaccine-induced harm is rigorously investigated. They consider patterns in reports to the Vaccine Adverse Event Reporting System (VAERS), as well as conducting proactive studies. For example, CDC sponsors the Large Linked Database project with the assistance of several large managed care plans on the West Coast.[1, 2, 4]

People have objected to vaccinations since the days of Jenner's smallpox vaccine, over 200 years ago.[1, 4-6] It is unrealistic to expect unanimous approval of the nation's vaccine policies. But Pharmacists have a professional duty to advise people on the best use of medications. Vaccines are just another kind of medication.

Table 1 provides some reasoned responses to general questions about vaccine safety that the public may have.[1, 2, 4] Table 2 lists telephone and Internet resources about vaccine safety.

In dealing with criticism of any medication, it is wise to ask some fundamental questions.[7] For example, does the source of the criticism take responsibility for the information it relays? Does the information stand up to critical appraisal? Does the information come from credible, referenced sources? Are the authors of the studies named?

Have the limitations of the studies been acknowledged? Could it be that details are cited out of context? Are conspiracy theories claimed, especially claims that the truth is being suppressed? What are the motives of the information source? And old adage suggests that "if it's too good to be true, it probably isn't." The opposite often holds as well: If it seems so bad you wonder how we tolerate the problem, it probably isn't a real problem.

Some of the specific recent complaints about vaccine safety appear in Table 3, matched with brief answers to explain the considered opinions of the nation's vaccine experts.[1-3, 5, 6, 8-9] I have never met a vaccine expert who did not readily seek vaccination, personally or for his or her family.

Teasing questions like "Are vaccines for your children safe? Tune in at eleven . . . " attract an audience. But shallow news stories do a disservice to the public. The journalistic tradition of balancing pro and con viewpoints may not be the best way to present opposing views that have differing degrees of factual basis.

The public needs help in separating the wheat from the chaff. They need help discerning when an allegation is premature, incorrect, or blown out of proportions. Understanding the facts about vaccine safety is the first step in explaining how benefits outweigh risks.

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Table 1. Inquiries about Vaccine Safety and Pharmacists' Potential Responses

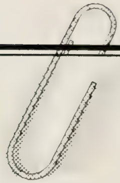
Inquiry	*Response*
"Getting vaccinated worries me."	"I'm glad you're asking questions about using medicines. Let's talk about how vaccine safety is monitored."
"I've heard about dangerous side effects from vaccines. How can the government allow these vaccines to be used?"	"I checked into how the CDC and FDA watch for vaccine side effects. They use several different monitoring programs and work with manufacturers to ensure production quality. Also, these vaccines have been used for many years with great success and with a solid track record."
"Isn't it terrible that vaccines harm people?"	No drug is perfect. Every drug has side effects. The key question is whether this vaccine's side effects are outweighed by the dangers of the infection. Your risk of a bad event after vaccination is far less than your risk if you stay vulnerable to this infection." *Or*: "The inconvenience of vaccination is more than balanced by the benefit of staying healthy, rather than being hospitalized with the infection."
"Who decides which vaccines to use?"	"The nation's experts at the CDC, the national societies of physicians, and authorities at major universities agree that this vaccine is worthwhile in cases like yours. The CDC wrote this Vaccine Information Statement (VIS) about this vaccine. Would you like me to explain what any of this means or help you find more information?"
"Would you take this vaccine? Would you let one of your kids get it?"	"I got this vaccine a few years ago, and my kids will get it when they reach the right age."

Table 2. Resources for Vaccine Safety Information

Centers for Disease Control and Prevention	www.cdc.gov
Vaccine Information Hotlines	800-CDC-SHOT, 800-232-2522
Fax Information Service	888-CDC-FAXX
Vaccine Safety: What You Need to Know	www.cdc.gov/nip/vacsafe
Six Misconceptions About Vaccination & How to Respond to Them	www.cdc.gov/nip/publications/6mishome.htm
Immunization Action Coalition	www.immunize.org
Stories of Victims of Vaccine-Preventable Diseases	www.immunize.org/stories/unprot.htm
Infectious Disease Society of America Vaccine Initiative	www.idsociety.org/vaccine/index.html
Institute for Vaccine Safety at Johns Hopkins School of Public Health	www.vaccinesafety.edu
Canadian Immunization Guide, 5th ed. Health Canada;1998	www.hc-sc.gc.ca/hpb/lcdc/ publicat/ immguide/ index.html
Update: Vaccine-Preventable Diseases	www.hc-sc.gc.ca/hpb/lcdc/publicat/vacprev/index.html
Comparison of Effects of Diseases and Vaccines	www.hc-sc.gc.ca/hpb/lcdc/publicat/immguide/comp-e.html

Table 3. False Allegations About Vaccine Side Effects and Rejoinders

Allegation	*Rebuttal and Conclusion*
Hepatitis B vaccine causes multiple sclerosis	Rebuttal: No objective evidence supports this claim. Accusation based on anecdotes. World Health Organization and National Multiple Sclerosis Society agree that there is no evidence of a link.
Hepatitis B vaccine causes newborn deaths	Rebuttal: Critics analyzed VAERS reports incorrectly, failing to note that the VAERS database can contain multiple reports of the same adverse events. Also failed to acknowledge that the current level of newborn deaths is comparable to level before this vaccine was used in infants.
Hepatitis B vaccine is not needed by children not at risk	Rebuttal: All children are vaccinated against polio and other preventable infections, although only a fraction of children are likely to be infected. We cannot predict who will be infected with hepatitis B virus during their lifetime, so universal vaccination is prudent for all children. Conclusion: Hepatitis B vaccine is 95% effective at preventing infection. Vaccination prevents liver disease and hepatocellular cancer.
Whole-cell pertussis vaccine causes brain damage	Rebuttal: Independent panels found that brain damage after whole-cell pertussis vaccine is either nonexistent or so rare that it is hard to distinguish from the background rate of neurologic problems that have always affected certain children. Conclusion: Pertussis vaccine prevents a dangerous respiratory infection of children.
Measles and measles-mumps-rubella vaccines cause inflammatory bowel disease and autism	Rebuttal: Studies claiming associations are flawed by selection bias and biological inconsistencies. Conclusion: Vaccination against measles, mumps, and rubella prevents three dangerous infections.
Vaccination early in life predisposes children to diabetes	Rebuttal: Claim based on simplistic "ecological" comparison of one country to another, without adjusting for multiple alternative explanations. Conclusion: childhood immunization has added many years to a person's life expectancy. Vaccination is beneficial both to individuals and to communities.



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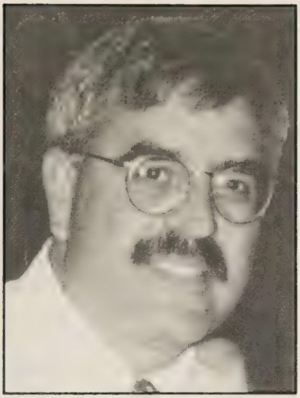

By Phillip L. Marsiglia

Not that long ago, a practicing physician had ample time to diagnosis an illness, prescribe a treatment and monitor the patient's response. In addition, he had the time to lend a sympathetic ear and a consoling word, often in the patient's home. The community pharmacist's day was spent filling physician's prescription orders, often compounding the ingredients extemporaneously, assisting patients with OTC selection, all while dispensing free medical advice to anyone who walked through the door with a concern. Because of the pharmacist's accessibility, he often served in a triage roll, advising patients of the appropriateness of self treatment or the necessity of seeking care from their physician. The image of the neighborhood druggist talking with his customers around the soda fountain has unfortunately, like the physician's house call, disappeared from our collective consciousness.

Times have changed; physicians squeezed by a stringent managed care environment are forced to compress their medical duties into 15-minute office visits. Pharmacists, confronted with rapidly declining fees from PBM's (pharmacy benefit managers) and HMO's, are forced to fill more prescriptions in less time or go out of business. These changes are occurring at the same time that disease management is becoming more complex. Multiple drug regimens with increasingly potent agents require constant monitoring and frequent alteration. Although each profession has enlisted lesser-educated personnel (Physician Assistants and Pharmacy Technicians) to reduce the burdens in their respective practices, a resource that would naturally compliment the physician's extensive knowledge in diagnostics and disease management has been largely ignored. At a time when the need for assistance with drug therapy management is greatest, the interaction of the pharmacist with the physician, at least in the ambulatory setting, has been relegated to a discussion of which drug in a therapeutic class is covered on a patients prescription drug card.

The time has come for physicians and pharmacists to join together in a collaborative fashion, and through the framework of a Medication Management Agreement, draw on the strengths of each profession to provide comprehensive drug therapy management.

Although the concept of physicians and pharmacists practicing under the terms of a medication management agreement are commonplace in the institutional arena, such arrangements in the ambulatory setting are relatively new although their prevalence is booming. According to Carmen Catizone, executive director of the National Association of Boards of Pharmacy, 23 states have some sort of provision for formal medication management agreements between pharmacists and physicians. In the remaining 27 states, the respective Boards of Pharmacy and pharmacy organizations are seeking to expand the scope of pharmacy practice by either legislation or the reinterpretation of current laws to allow agreements to occur. Medication Management Agreements, also known in some states as Collaborative Practice Agreements, or more accurately, Collaborative Drug Therapy Management Agreements, take as many forms as there are states in which they have been implemented. Although no uniform definition exists, most Medication Management Agreements enable a pharmacist, through the voluntary and limited delegation of authority by a physician, to monitor and evaluate drug therapy and to make specific types of changes to the therapy when appropriate. Although not always, the agreement is usually limited to a single patient, with a specific diagnosis and the scope of the pharmacist duties and responsibilities are defined in an agreed-upon treatment protocol. Voluntary agreement can also be developed between pharmacists and other authorized prescribers.

An example of a Medication Management Agreement might work as follows:

The physician writes an order for a pharmacist, who he has previously entered into a Medication Management Agreement, to provide cholesterol management for one of his patients. The order, which serves as a certificate of medical necessity, enables the pharmacist to:

- Interview the patients in respect to diet, lifestyle and family history
- Advise the patient as to the importance of drug and diet compliance
- Order appropriate laboratory test to monitor blood lipid levels
- Modify the dose of a physician initiated drug, according to pre-established protocols or treatment goals
- Document intervention in the patient's medical record

Treatment protocols, which serve as management guidelines, delineate the pharmacist's duties and responsibilities. The protocols, which are jointly agreed upon by the pharmacist and physician, are usually drawn from already established disease management guideline of the National Institutes of Health or from other medical specialty groups such as the American Heart Association.

Examples of Medication Management Agreements currently being practiced include:

- Cholesterol Management
- Smoking Cessation
- Anticoagulation Therapy Management
- Diabetes Monitoring and Management
- Nutrition and Wellness
- Asthma Management

Utilizing pharmacists as drug therapy managers makes good healthcare sense.

- Pharmacists are the only health care professionals whose primary focus of study is medication. Contemporary pharmacy education, with its emphasis on pharmacology and pharmacotherapeutics makes pharmacists uniquely qualified to assist physicians in drug therapy management.

- Because pharmacists are usually more accessible than other health care professionals, they are able to spend more time educating patients about their medications and the importance of adherence with a treatment regimen. According to Ray E. Marcrom, PharmD, a pharmacist collaborating with physicians since 1978, "Patients' reactions to these expanded services are nearly always positive." Patients want more information in an understandable form and are often hesitant to ask the physician.

- According to numerous studies, problems associated with the misuse of prescription medications, in terms of morbidity, mortality, and treatment, cost society tens of billions of dollars annually. In a 1995 study by Johnson and Bootman, limited to the ambulatory setting in the U.S. alone, the estimated cost was reported to be $76 billion. In the same study, a savings of 40% could be realized when pharmacists are involved with the management of the drug therapy.

- The services provided by a pharmacist in a medication management agreement are typically services that the physician does not provide in the office or a service that is provided at a significantly lower level because of a lack of time or reimbursement. By delegating some of the responsibility for drug therapy management to the pharmacist, physicians free up time that can be used to increase patient load, often with a corresponding monetary increase to the practice.

Diminishing Barriers to Medication Management Agreements

Most of the barriers to the establishment Medication Management Agreements have been overcome. Though not always the case, opposition from individual practicing physicians is no longer common. Once physicians accept the fact that these agreements are meant to augment, not compete with their practices, most physicians welcome the added benefit that the agreements can bring to their patients. Although there continues to be opposition to these agreements with some State and National Medical Organization, acceptance is steadily increasing. The American Medical Association has generally supported such agreements, so long as the physician maintains control of the patient's total care. PhARMA, which was an early opponent of Medication Management Agreements, now generally supports the agreements as long as the terms of the agreements are specific to a single pharmacist and patient and that the agreement prohibits therapeutic substitution. Probably the most significant barrier to the establishment and success of these agreements concerns the issue of reimbursement for the pharmacists' services. Third party payers have been hesitant to reimburse for these services without assurances that the pharmacist's level of training is sufficient to provide them. Certificate training programs, which provide pharmacists with advanced training in specific disease state management, appear to be overcoming the reimbursement barrier.

Conclusion

The enactment of laws permitting the establishment of Medication Management Agreements is consistent with the shifting paradigm in health care delivery. Market-driven forces are causing the entire health care system to become more collaborative. Specialization of care is moving to primary care and competitive, individual providers are being replaced by cooperative team providers. Pharmacists will be enabled to more appropriately utilize their skills as drug therapy managers. Physicians, while not relinquishing their control over total patient care, will be allowed to concentrate their efforts in the areas of medical diagnosis and disease management. Clearly, patients are the group with the most to gain from physician - pharmacist medication management agreements. Patients who have seen managed care restrict easy access to their medical providers, will be able to establish a new relationship with a more accessible practitioner whose focus is the monitoring and evaluation of the patient's drug therapy. By educating patients and minimizing adverse drug reactions, increased adherence with the treatment regimen will be maximized and disease management goals will be more completely met. The relationship with the pharmacist will compliment, rather than compete with the patient's already existing relationship with his/her physician. By combining the strengths of both professions, health care delivery will be enhanced as an aging population enters the new millennium.

Acknowledgement

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This article was also published in the Fall 1999 Issue of "*The Maryland Family Doctor*", Volume 36, Number 2

To our members,
Thank You for your loyal support this year!

Happy Holidays to you and your loved ones from The Maryland Pharmacists Association!

This has been an especially exciting year, as we're celebrating our 117th anniversary.

As this year draws to a close, we want to thank you for your continued support. We wouldn't be where we are today without loyal members like you!

We look forward to serving you for many years to come, and we wish you and your family a very healthy, happy and prosperous 2000.

May all your Holiday Dreams Come True!

Adult Learning

If You Learned More, Would You Earn More?

By Ronald Gross

'Learning is good' was the fatuous inscription on the pedestal of the statue of the college president in *Animal House*, the 1978 spoof of student life starring John Belushi. The credo always gets a hearty laugh from movie audiences—perhaps because some of them have attended conventions at which lifelong learning is extolled in this kind of hollow way.

But what if we could show that managers who continue to learn and grow actually earn more, advance faster, and get more gratification out of their work?

That would be convincing—so when I address this topic for association conventions, I like to provide audiences with data, not just homilies. How much difference does continual learning make—in dollars and sense?

My data comes from John Kotter and his cadre of Harvard MBAs from the last 20 years—men and women who are currently entering the upper ranks of management in major corporations or making their mark as entrepreneurs.

Kotter, who is a professor of leadership at Harvard, has studied the detailed work histories of these top MBAs. They are certainly among the best-prepared to cope with a changing work environment. Surely these Harvard graduates, who have literally received "the best education money can buy," could simply use what they learned at the university to achieve success in their careers.

However, scrutinizing their careers, Kotter made a startling discovery about why some of them did far better than others. Those who reported that they had learned from a wide range of experiences were consistently in the top 50 percentile of their classes in earnings and achievement.

"What is so interesting about these people," Kotter wrote, "is their ability to turn turbulence in their business environments into something useful. New competition, raids, reorganizations, and the like become (for them) not just destructive, but an important source of growth. Because they look honestly at their successes and failures, they learn and grow."

Such learning was not confined to these people's careers. Kotter noted that many of them whose careers seemed untroubled actually had to contend with grievous personal and family problems, such as illness, death, and divorce. In addition, among those individuals the capacity to learn, cope, and move on differentiated those who overcame their trials from those who foundered.

Kotter even calculated the advantage you can gain from learning continually—and the cost to your career if you neglect doing so. Even a slight edge in growth will pay off big as your career proceeds.

Let's take a hypothetical manager, Alice, who's pro-active about learning continually—both in the classroom and from her experiences in her career. Compare her to another manager, Bob, who does his work but doesn't make the effort to really learn and grow. If Alice is just 5 percent more effective in her continual learning than Bob, she will end up three times as competent by the time she's being considered for a move into top management.

If you'd like to see the figures, send me your business card, marked "Learning Payoff," to Gross and Gross Associates, 17 Myrtle Drive, Great Neck, NY 11021.

Ronald Gross is an author and speaker specializing in interactive presentations for association conventions. To receive his regular Dose of Gross e-mail, contact him at GrossAssoc@AOL.com.

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The Experiential Learning

Theresa Wang, UMB Pharm.D. Candidate

Increase prescription costs have fueled the growth in pharmacy benefit managements (PBM). Using lowest cost to provide the best outcome has become the goal of all health providers. PBMs help to attain this goal by integrating clinical and financial data to perform drug utilization review, create disease management programs, develop treatment guidelines, produce formularies, and evaluate generic substitutions based on pharmacoeconomic models.[1, 2]

Interest in PBMs led me to sign up for a rotation with Advance Paradigm, Inc., (AP), to learn the roles of a pharmacist in such a setting. During the rotation, I had the opportunity to observe first hand the day to day operations of a pharmacy benefit manager. Advance Paradigm is an independent company, covering close to 27 million lives in the US. They provide a broad range of clinical, mail, data, and customer services through health benefit management, disease management and clinical research services. AP supports a broad range of clients—from HMOs, PPOs, Blue Cross Blue Shield organizations, insurance companies, and third-party administrators.

Advance Paradigm's headquarters is located in Dallas, Texas, along with its mail order house and claims processing center. The office at Hunt Valley, Maryland is the clinical service site. It provides services such as disease management, formulary development, Drug Utilization Review (DUR), P&T meeting support, and benefit designs to each client. Disease management is the newest service, covering the common chronic diseases. Clinical pharmacists are in charge of researching available information on the treatment of each disease. Information could come from published journal articles, or established guidelines. It is then incorporated into a treatment algorithm, which outlines treatment options step by step. This information is passed on to clients, who then pass it along to its physicians. Formulary development process varies for different clients. Each client can follow the Advance Paradigm's national formulary or request individualized formularies to fit their needs. DUR is done with data from the claims processing center in Dallas, to review drug usage of each patient covered by separate clients. It takes claims data and organizes them into meaningful tools for each client. It also supports the mail order house in Dallas by providing therapeutic substitution recommendations. In addition to the clinical department, the Hunt Valley office also houses the contracting department. The contracting department negotiates contracts with pharmaceutical companies for rebates, and also acts as the liaison between client and pharmaceutical companies for formulary production. The clinical and contracting departments work very closely in order to provide the most effectively therapeutic options with the most financially beneficial methods to their clients.

As a pharmacy student on rotation, I participated in pharmacy and therapeutics (P&T) committee meetings, met with pharmaceutical company representatives while they presented their products, attended weekly pharmaceutical rounds with Pharm.D. residents, sat in on a company planning meeting, and talked with various people in different departments. I worked on a variety of projects during the rotation, mainly to get a taste of the job. I wrote a monograph for use at a P&T meeting, developed a bulletin on appropriate usage of medication for physicians, performed literature search, participated and prepared a journal club presentation, and gathered information for their mail order house.

Overall, I enjoyed my rotation at Advance Paradigm. I learned more by active participation than I would have from lectures. Nonetheless, four weeks gives only a taste of all the services they provide.

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Editor's Note:

The University of Maryland is looking for more preceptors. *The Experiential Learning* is a series of structured learning and training activities during which students work under the supervision of experienced preceptors (pharmacy practitioners who have faculty appointments) and academic faculty in a variety of health care settings. Students obtain and apply knowledge and skills necessary for successful delivery of pharmaceutical care and develop competence, confidence, and maturity as responsible professionals. If you would like more information on becoming a preceptor, call Richard Rumrill, Director of Experiential Learing, at 410-706-4192.

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The Benefits of Membership

Representation on Pharmacy and Healthcare Issues on both a regulatory and legislative level. The unique position of MPhA enables the Association to more effectively assert the position of its members than do national or specialty associations. The MPhA's Executive Director attends every monthly meeting of the Board of Pharmacy, and participates on behalf of MPhA on various committees consisting of pharmacists and other health care professionals. Regulations which affect pharmacists, both directly and indirectly, are influenced through the actions of MPhA and its Legislative Committee. MPhA was actively involved in the revision to the Pharmacy Practice Act, and will continue this involvement throughout the 2000 Legislative Session.

A toll-free hotline (800-833-7587) to answer the practice-related questions of members. Due to the very nature of a professional association, the resources available to MPhA are greater than those available to individual practitioners. If they cannot answer the question or concern based on MPhA's resources, the MPhA staff will try to find the information needed by the member.

Specialized Education and Training, in preparing for pharmacy's future. Year after year, the MPhA Mid-Year Meeting offers up-to-date continuing education which no practicing pharmacist can afford to miss. The Annual Convention is a series of continuing education programs focusing on the issues facing pharmacists. In addition, there is always plenty of time to relax and enjoy. MPhA convention attendees can earn approximately 13 continuing education credits toward their licensure renewal requirement. Our business meetings are scheduled to give everyone a chance to participate in the Association's policy decisions.

The Maryland Pharmacist and MPhA Newsletter, published quarterly and monthly, respectively. In the recent past, these publications have dealt with issues which include the revisions to the Pharmacy Practice Act, new third party plans, new federal laws, settlement of the discriminatory pricing lawsuit, and recent policies and decisions from the Board of Pharmacy.

A way to network with pharmacists in different locations and different practice settings, both hands-on and through other State Pharmacy Associations. Members have the unique opportunity to meet and develop professional relationships with practitioners in all types of health care settings. By planning and acting together, pharmacists can use a combination of knowledge and experience to benefit not only the profession, but also patients.

Pharmacy Laws and Regulations Governing the Practice of Pharmacy in Maryland, a copyrighted publication available to members at a discounted price. Once the entire compilation is purchased, annual updates are available, with the cost of these discounted for members. The revisions to the Pharmacy Practice Act has changed the laws which define the what and how of pharmacy practice in Maryland. All parts of the revisions passed during the end of the previous year's Legislative Session will be included in the current edition.

Other Services and Programs are available as membership benefits. MPhA members are eligible for discounted registration fees for Association meetings and programs.

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The Maryland Pharmacists Association has contracted with many corporations to offer member only discounts and benefits to assist you with your professional, business and personal expenses. They include:

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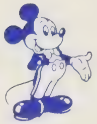

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Membership Renewal

For your convenience a membership investment is included in this issue of the *Maryland Pharmacist*. See page 21. Memberships will expire the end of December. Take this opportunity to renew before December 31 and be eligible to ***win a free two-day registration for the Mid-Year Meeting*** valued at $ 150. All members who renew before the deadline will be entered in the drawing. You can charge your dues! Fax It! It's Convenient and Quick! Our fax number is 410-727-2253.

If you have already renewed your membership, please pass the membership investment form along to a friend or colleague who is not currently a member. When they join MPhA and pay their dues you will receive 10% off your 2001 membership dues.

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O	☐	Other

Important Tax Information

Dues for MPhA are not deductible as charitable contributions for Federal Tax purposes. However, they may be deductible as ordinary and necessary business or miscellaneous expenses. Because of tax law changes affecting association membership dues deductibility, you may not deduct any portion of your dues which goes towards lobbying local, state, or national government agencies. MPhA has determined that the deductibility of your MPhA dues is limited to no more than 85% of your total dues.

Indra Huber, MS, ND, BSc

Treat Seasonal Allergies/Sinusitis and Rhinitis with Herbs

Naturopathic medicine involves several modalities, all geared toward the general well-being of the patient. Some treatments, to name a few, involve: nutraceuticals, herbals, therapeutic fasting, vitamin and mineral supplementation, homeopathy, acupuncture, Chinese medicine, massage, hydrotherapy and therapeutic exercise. Usually, synthetic drugs and surgery are not used in naturopathy.

Astragalus

Chinese Astragalus, *Astragalus membranaceus,* belongs to the family of peas and the group of vetches. It has a stimulant effect on the immune system. It stimulates the production of interferon, thus helping decrease the duration of the common cold and other viral infections. It helps boost stem cells in the lymph tissue and bone marrow as well. Astragalus has been the classic herb in the Orient to "tonify the Spleen, Blood, and Qi." The dosage is 4 mg/day of the root or 1 gm/day of the extract. No contraindications are known, however, caution should be used in patients with overactive immune systems or autoimmune disorders.

Echinacea

There are three different species of Echinacea (*E. purpurea, E. angustifolia, E. pallida*), each containing various levels of glycosides, polysaccharides and sesquiterpene esters as well as numerous other substances.

Echinacea boosts the immune system, reduces inflammation, and has antibacterial, antiviral and antifungal action. Echinacin in *E. purpurea* has cortisone-like action which helps in bronchitis and sinusitis. By stimulating the immune system, allergies may be kept under control by the individual's own responses. Echinacea should be cycled—a few weeks on and a week off— for optimal response. Contra-indications include kidney disease, autoimmune disorders or allergies to ragweed or pollen.

Ephedra

Ephedra, or *Ma Huang*, is an alkaloid which acts as a bronchodilator by stimulating the sympathetic nervous system. It reduces catarrh in the upper respiratory tract. It has been used to treat hayfever, asthma and sinus congestion. The isolated ephedrine can increase blood pressure and thus is contraindicated in patients with high blood pressure, as well as patients taking thyroid, CNS stimulants or other CNS drugs. The whole plant actually contains several alkaloids which balance out the stimulatory effect. The maximum dosage is 8 mg three times daily.

Garlic

Garlic appears to be a safe, inexpensive and effective treatment for many medical problems, including colds, flu and bronchitis. The volatile oil allicin is a strong antibiotic and is considered equivalent to penicillin in Russia. It is effective against *Staphylococcus* and *Strepococcus* bacteria as well as fungi. This aids in the sinusitis often associated with allergies. Garlic can be taken orally or prepared as a steam inhalation for bronchial infections. A topical liniment can also be made by mixing garlic, olive oil and lanolin; it is then rubbed on the chest.

Goldenseal

The Iroquois and Cherokee Indians used this plant for many conditions due to its anti-inflammatory properties. The plant contains alkaloids (hydrastine and berberine) which act as astringents to reduce mucous membrane inflammation. Hydrastine also acts as an antitussive. Thus, throat and sinus problems associated with mucous can be treated with goldenseal.

Licorice

Licorice contains a glycoside, glycyrrhizin, which acts like the adrenal steroid cortisone. Thus, it has anti-inflammatory properties which aid in allergy treatment. It also has a demulcent action, useful in stopping coughs and upper respiratory complaints. Horehound candy drops contain licorice to relieve a sore throat. The dosage is 600 mg/day of deglycyrrhizinated extract.

Marshmallow Root

This herb is mucilaginous and calcium-rich and relieves inflamed mucous membranes in the throat, lungs and skin. It can be given as a tea, tincture or as capsules for bronchitis, congestion and coughs.

Nettles

Stinging nettles (*Urtica dioica*) is an excellent treatment for allergic rhinitis due to its antihistaminic properties. The plant actually contains histamine, along with the minerals iron, magnesium, sulphur and vitamins A, C, B^2 and chlorophyll. These substances have been shown to reduce sinus congestion as well as sneezing. The usual dosage is 750 mg extract daily.

Essential Plant Oils

Essential oils can be used topically to boost immune function as well as to work as antibacterials for seasonal allergies and other types of infections. The oils appear to block oxygenation of bacteria; thus, the bacteria suffocate. Most oils are absorbed through the skin in 20-60 minutes. A study published in 1971 showed that lemongrass oil was more effective against *Staph. aureus* than streptomycin or penicillin.

Eucalyptus

This oil is used as an expectorant in respiratory infections, bronchitis, colds and sinusitis. *Eucalyptus radiata* works as an antiviral. *Eucalyptus globulus* is a mucolytic and expectorant, used in heavy congestion. Eucalyptus can be used as a chest rub or as an inhalation via a vaporizer.

Inula graveolens

This oil has a relaxant effect on the muscles of the respiratory tract, thereby reducing inflammation and coughing. It is used via inhalation.

Thyme

Thyme has been demonstrated to inhibit *Klebsiella pneumoniae* and *Candida albicans*. It is quite potent, so only a small amount is used as a chest rub. This oil usually should not be used for more than one week.

Conclusion

There are many other ways one can treat seasonal allergies naturally. Increasing vitamin intake (e.g., Vitamin C acts as an anti-inflammatory in the lungs at higher dosages, CoQ10 acts as an antihistamine) and using a negative ion air cleaner are non-invasive methods of treating some symptoms.

For those patients who wish a complementary way to treat their seasonal allergies, they may look to naturopathic medicine for help!

About the Author

Indra Huber, MS, ND, Bsc

is a practicing pharmacist and a Doctoral candidate in Naturopathic Medicine. Huber is a Board Member of the Academy of Pharmacy Specialties and serves on the Editorial Review Committee for CPhA.

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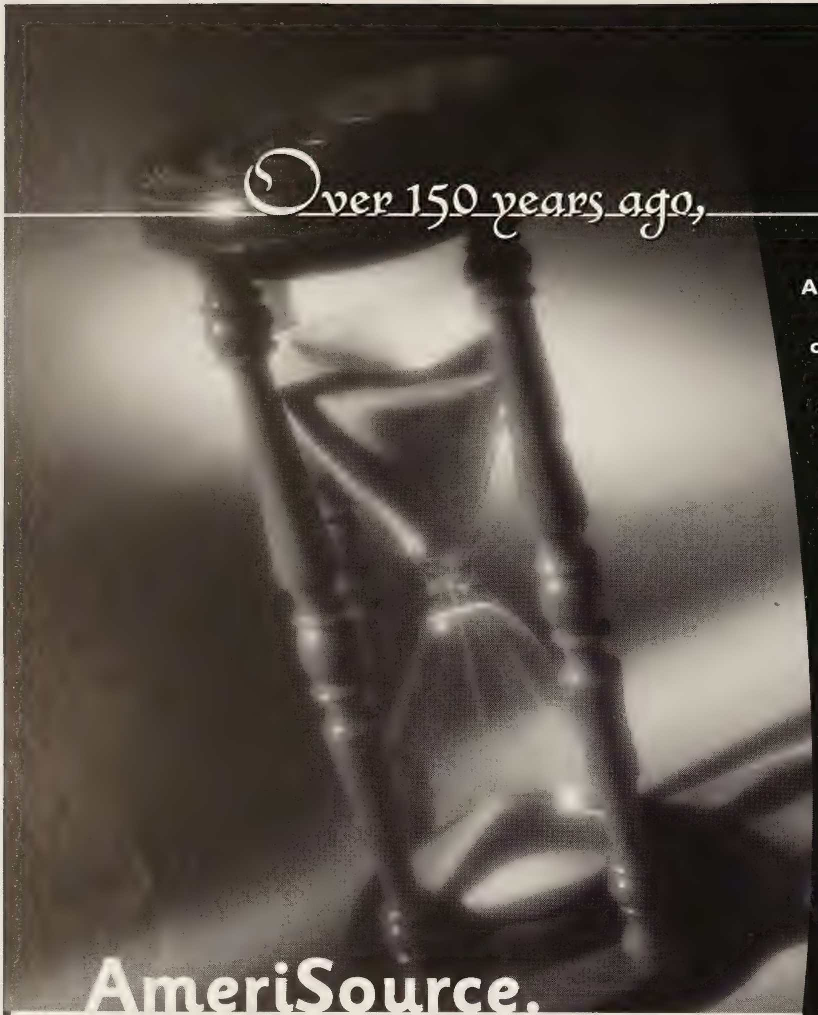

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Interactions...
Pharmacists Against Tobacco!

MPhA and the University of Maryland School of Pharmacy have kicked off a collaboration to attack the state's number one health problem – the use of tobacco. The links are unassailable between tobacco and major killers such as cancer, heart disease, and emphysema. Maryland Governor Parris Glendening has committed $1 billion over the next 10 years to the fight against tobacco and cancer. Two state-wide task forces have been established to coordinate the effort. Pharmacist Arnold "Skip" Amass serves on the Task Force to End Smoking in Maryland and David Ramsay, President of the University of Maryland, Baltimore, serves on the Task Force to Conquer Cancer. These groups will recommend to the Governor the process by which the tobacco funds will be allocated to achieve the goals.

As soon as the Governor announced his plans this summer, MPhA and the School decided to collaborate. MPhA Executive Director Howard Schiff sits on a School of Pharmacy Steering Committee chaired by Dr. Robert Michocki to coordinate activities. During the month of September, the two state-wide task forces held public hearings on 17 occasions throughout the state of Maryland seeking suggestions from the public about problems that needed to be addressed through the use of tobacco settlement funds.

Pharmacists and pharmacy faculty appeared and testified at every one of these hearings.

Time and again, our representatives hammered on key points:

- Pharmacists can be key players in the war against tobacco
- Because of accessibility and expertise, pharmacists can successfully mount smoking cessation programs.
- Pharmacist-led educational efforts should seek to stop smoking before it begins through programs in elementary and middle schools.
- Disease prevention and detection campaigns should be mounted using community pharmacies as an accessible way to get to the public.
- The School of Pharmacy has the expertise to develop and implement addiction prevention and treatment programs.
- Pharmacy faculty has the expertise to plan and evaluate public education and intervention programs.
- The long-term solution to cancer and other devastating health problems lies in research to determine underlining causes of disease. About one-third of the ongoing research in the School of Pharmacy is now related to cancer.

The Governor's task forces are expected to report in November by suggesting specific areas in which requests for proposals will be issued. MPhA and the School are prepared to evaluate these RFPs and to respond as appropriate. In the interim, the steering committee is working to develop our own initiatives that either serve as responses to RFPs or as the basis for our anti-tobacco activities.

MPhA has formal policies opposing the sale of tobacco in pharmacies and for promoting smoke-free environments. Wherever pharmacists appeared at the September hearings, panelists asked, "why do pharmacies continue to sell cigarettes in the face of over-whelming evidence of their harmfulness?" Our representatives were careful to point out the policy of MPhA and the fact that corporate owners of pharmacies determine whether or not cigarettes are sold. After all, tobacco products remain legal in Maryland and are, in fact, the source of significant tax revenues.

The School of Pharmacy will be in a strengthened position to carry out research and oncology with the completion of the Health Sciences Facility II on our campus in three years. The School will share research space in that building with the School of Medicine.

The anti-tobacco and conquer cancer initiatives in Maryland provide an unparalleled opportunity for cooperation between practicing pharmacists in both basic science and clinical faculty. MPhA and the School of Pharmacy plan to exploit this opportunity to the fullest!

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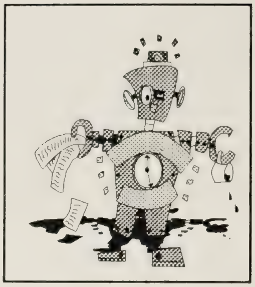

Mark Your Calendars!

The Maryland Pharmacists Association
2000 Mid-Year Meeting

Saturday, February 5 and
Sunday, February 6, 2000

The Inn and Conference Center UMUC
College Park, Maryland

Happy Holidays

A Different Road

Glenn Lichtman, P.D.

As you make that familiar drive to the same pharmacy you have worked in for years, you may not be aware that not all pharmacists are like you. Some pharmacists prefer variety, flexibility, fresh challenges, and a new environment.

When I am asked to describe the 'typical' PharmaSTAT pharmacist, I usually describe the 70 year old female that just delivered her first baby, working 5 to 50 hours per week. No, you do not have to read that again, what you thought you saw is correct. It's just that there is NO typical employee at our company. We employ men and women, pharmacists and technicians, aged 25 to 81. Our pharmacists have skills in Retail Pharmacy, Hospital Pharmacy, Long Term Care Pharmacy, Home Health Pharmacy, Managed Care Pharmacy, and any other practice site that ends with the word pharmacy.

Over the years, we have encountered many people who prefer working for our company than working for a traditional pharmacy. Some work full time for us, some part time, and some *very* part time. Some work for us at only one work site, but others prefer the variety of multiple work sites. Most of our professionals started their careers with traditional jobs just like yours, but for one reason or another, became disenchanted with their traditional jobs, and came to our company seeking employment. The reasons for the change in environment are varied, and I will tell you about some of the types of pharmacists who prefer the traveling life.

The Professional Student -

Never satisfied, this pharmacist is always looking for the next hot career choice. Over the years we have had pharmacists working for us that are in law school, med school, MBA programs, acupuncture school, and other school programs. We also have seen our share of individuals that are taking real estate courses, travel agent programs, and writing courses. Future stockbrokers, actors, and consultants have worked for us while pursing their future careers. The appeal of our flexible schedules appeals to this group. If they need time off for courses or study, we can schedule them accordingly.

Looking for the Ideal Job -

Some pharmacists become disenchanted with their current work place, and find it unbearable to stay while looking for a better position. For these pharmacists, we are a safety net. They know we can provide steady employment while they are looking for their ideal position. Often we are able to find a "temp to perm" position that suits their needs and desires. Not only does the prospective new employer get to see the pharmacists work, but the pharmacist also gets to try on the new position before making a commitment. This is also called "try before you buy," and is the hottest trend for permanent placements of pharmacists. Not only are staff positions obtained by temp to perm, but we have also placed pharmacy directors, managers, and supervisors with this method. And earning a steady income while searching for the ideal job is not a bad side effect.

And Baby Makes Three -

I am not sure how a new mom balances pharmacy work, baby, housework, and husband in her life, but I have seen it done enough to realize that it can take a toll on one or more parts of the equation. For many of these new moms, "temping" is the ideal way to keep up with the changes of our profession, bring in extra money, and still spend that precious time with the baby. The moms just decide which day or days they would like to work, give us a mileage radius, and we match up their skills with the positions that fit their requirements. As the baby gets older, they can ease back into full time, or stay part time. Mom's choice.

On the Road Again, Just Can't Wait to Get Back on the Road Again -

And there are those who just don't want to put down roots. Some people just crave variety and new environments. These are the people who never order the same lunch two days in a row, who buy a new car not because the old clunker is falling apart, but just because they are tired of the old one. They don't just enjoy variety, they thrive on it. Learning a new computer system does not intimidate them, it stimulates them. Some of these *road warriors* prefer to drive to work from their house every day, some drive from their hotel. The idea of walking into a pharmacy that they have never set foot in before is what makes their careers stay fresh. Some would call these professionals mavericks, some call them hired guns (or would that be hired spatulas?). Whatever the label, the pharmacist or tech is always welcomed with open arms. They fill the holes in a pharmacy schedule that would either go unfilled, or be filled by a *very* unhappy employee. Some of these jobs are in remote areas, and include mileage expenses, lodging, and food allowances. The job can last a few days, or a month, but is usually in a remote area with limited amenities other than the hotel, a restaurant or two, and a mall. But these pharmacists aren't there to sightsee. They are usually extroverts that rarely end up eating at the diner, but are usually invited to someone's house, and become immersed in the local culture rather quickly. They know all about aunt Sally's bursitis, the Kelley's new baby, and the joy and tragedy of the local life. Then just as quick as they arrived, they are gone, off to a new adventure.

And the Current World Record for Pharmacy Licenses is -

I have no idea. But I hold four licenses, and have used them all within the last calendar year. I helped out a client in Philadelphia that *needed* to go to a golf tournament. I have traveled to rural Virginia, found wonderful people, and great barbeque (they don't use barbeque sauce in Virginia, did you know that?). I know the best areas of Washington, D.C., and the most frightening areas as well. I have worked in farm country in Maryland that was so rural, a man brought in pictures to show us the newest arrival in his life—a baby calf.

As for me, I spend most of my days in the office, so when I do work a site, I enjoy it immensely. I have worked in all practice settings over the years, and couldn't tell you which I like best. I have seen the best that pharmacy has to offer, and the worst. And despite what other pharmacists may say in public, if given the chance, most would make the same career choice all over again.

Glenn Lichtman is the owner and CEO of PharmaSTAT, the mid-Atlantic region's oldest and largest pharmacy agency. PharmaSTAT employs over 300 pharmacists and pharmacy technicians, and in addition to the mid-Atlantic region, provides pharmacists and pharmacy personnel at contract sites all over the country.

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Pharm/alert® Notes

Counseling Notes for Pharmacists

Getting Ahead of Head Lice

It's back to school again and the lice are lurking. Head lice (*Pediculosis humanus capitis*) are tiny wingless insects that happily feed on the human scalp. Even today, the presence of head lice is highly stigmatized—i.e., many people believe that lice are a sign of filth or of a low echelon of society. This is simply not true. Head lice can affect anyone, particularly young school children who have head-to-head contact and tend to share combs, brushes, scarves, and hair accessories. Head lice have no socioeconomic predilection.

Lice are adept at keeping out of sight. They are quite mobile on the scalp and capable of blending into their environment. The diagnosis of head lice is usually made by the identification of live lice *and* nits (tiny eggs, which are much more prolific than the adult lice).

While confirming lice infestation, look for both adult lice and their nits. Since adult lice move quickly, it is easier to spot the nits, which are more commonly found behind the ears and at the nape of the neck, close to the skin.

Itching is the primary symptom. Early infestations may not cause any visible skin reactions, but dermal infections such as pyoderma may occur, especially in warm, humid climates.

Parents are rarely prepared to receive the news when the school nurse, physician or pharmacist confirms the diagnosis. Many are devastated. The pharmacist has a unique opportunity to set parents at ease by explaining that lice infestation is not their fault. Lice appear in the most sanitary conditions, and there are several safe and effective treatments available.

The first step is to use an OTC pediculicide. OTC products include synergized natural pyrethrins and permethrin. Inform patients about the importance of following the directions that come with the medication. Since no pediculicide is 100% ovicidal, most experts agree that a second treatment may be necessary 7-10 days later. Combing the hair with a fine-tooth, metal comb specifically designed for lice and nit removal is an essential second step.

Some studies suggest that lice have become resistant to OTC pediculicides. For treating resistant lice, physicians have two options: lindane 1% and, more recently, malathion lotion 5%.

For parents, the task of cleaning the entire house appears more formidable because of the emotions stirred by the presence of lice. However, housecleaning need not be a frantic, in-depth performance, since lice do not survive away from a human host for more than a day.

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Continuing Education for Pharmacists

Volume XVII, No. 1

Patient Counseling: Prostate Cancer; Part 1: Introduction, Background, and Risk Factors

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Goals. The goals of this lesson series are to discuss prostate cancer and present information useful in counseling patients on the disease.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. identify probable causes including risk factors, pathogenesis, prognosis and symptoms of prostate cancer;
2. exhibit knowledge of drug and non-drug treatment options, and methods to control symptoms;
3. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to treat prostate cancer; and,
4. demonstrate an ability to counsel patients on prostate cancer.

A professional development program made possible by an educational grant from

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This lesson is the first of a two-part series. It examines the prostate gland; and pathogenesis, symptoms and risk factors of prostate cancer.

Prostate cancer is the most commonly diagnosed cancer in men in this country, and the second leading cause of cancer death in males. It accounts for more than 13 percent of all cancer deaths and more than 28 percent of all cancers in men in the U.S., claiming an estimated 39,200 lives in 1998. Only lung cancer has a higher mortality. It is more common in black males than white males, with 22 deaths per 100,000 and 14 deaths per 100,000, respectively.

Prostate cancer is rarely diagnosed before age 50, with a median age of 66 for diagnosis in the U.S. The risk of males developing the disease in the U.S. from birth to age 39 is one in 10,000; from 40 to 59 years of age, one in 103; and from 60 to 79 years of age, one in eight. At age 50, a man has a 42 percent chance of developing prostate cancer, and a 2.9 percent chance of dying from it.

Epidemiologic and screening studies performed in the past several decades have raised a number of important questions about the pathogenesis of this disease, but a definitive cause has not been established. Age-adjusted incidence rates as well as death from clinical prostate cancer vary dramatically from country to country. For example, one study reported a 25-fold increased incidence in American black males living in San Francisco compared to Japanese males in their home country.

Prostate cancer is increasing in incidence. The advent of improved screening procedures such as the prostate-specific antigen blood test and growing public awareness have raised questions concerning the cause(s) of prostate cancer as well as methods to screen for and prevent this disease. The ultimate goal of epidemiologic studies is to identify risk factors to guide disease prevention strategies.

The Normal Prostate

The prostate gland is a firm, elastic organ that reaches its normal adult size of about 20gm by age 20. It is the size of a walnut having the consistency of a pencil eraser. Located at the base of the bladder and in front of the rectum, it completely surrounds the proximal urethra. See Figure 1.

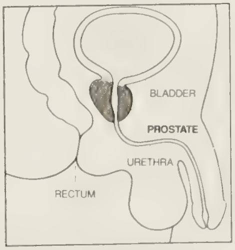

Figure 1. The prostate gland.

Table 1
Stages of Prostate Cancer*

A (I)	Occult; discovered incidentally at transurethral resection Asymptomatic Nonpalpable
B (II)	Macroscopic Clinically palpable but confined to gland
C (III)	Tumors that have extended outside the capsule of the gland to tissues around the prostate Seminal vesicles may contain cancer cells
D (IV)	Tumors have spread to regional lymph nodes or distant sites; metastatic disease

**American Urological Association*

Its purpose is to protect or enhance the functional properties of spermatozoa. For an average human ejaculate of 3.5 mL, the prostate gland secretes 0.5 mL. The gland may also help protect against urinary tract infections through secretion of the prostatic antibacterial factor (PAF).

Two other components of the glandular secretion are prostatic acid phosphatase and prostate-specific antigen (PSA). PSA is a protease involved in liquefaction of the seminal coagulum (ejaculate). Its concentration is increased by approximately 10 times in prostate cancer, and is the most important marker for the tumor. Prostatic acid phosphatase was used extensively as a marker prior to the discovery of PSA for diagnosis, staging, and monitoring of patients. The usefulness of PSA will be discussed in Part 2 of this series.

The gland is comprised of an anterior fibromuscular portion and posterior glandular segment. Three morphologically distinct zones of tissue are identified within the latter portion: the peripheral, central and periurethral zones. These layers of tissue are separated by a transition zone.

Testosterone. The principle hormone that regulates growth of prostatic tissue is dihydrotestosterone (DHT). About 80 percent of stage D prostate tumors (see Table 1) are androgen-dependent. Males who are castrated or whose pituitary gland atrophies before age 40 rarely develop prostate cancer.

Approximately 95 percent of testosterone is produced in the testes, with the remaining five percent released by the adrenal glands. Synthesis is controlled directly by secretion of gonadotropin-releasing hormone (GnRH). Also referred to as luteinizing hormone-releasing-hormone (LHRH), it is a product of the hypothalamic-pituitary gland. GnRH signals the pituitary gland to release luteinizing hormone (LH) which, in turn, binds to receptors in the Leydig cells of the testes where it increases synthesis of androgens, such as testosterone. Testosterone is metabolized into DHT, the active hormone. This conversion is catalyzed by the enzyme 5-alpha-reductase in prostatic epithelial cells.

Pathogenesis

Approximately 95 percent of all prostate tumors are adenocarcinomas (i.e., carcinomas of glandular epithelium) and occur in the periphery of the prostate. The remainder are transitional cell carcinomas, squamous cell carcinomas, and sarcomas. Tumors normally appear in the posterior peripheral portion of the gland. Metastases usually occur following spread of cells through lymphatic and blood vessels. Pelvic lymph nodes and the skeleton, particularly the pelvis and lumbar spine, are the usual sites. Less commonly, the liver, lungs, and adrenal glands may be involved.

Prostate cancer may have an unpredictable history. In some males, it may metastasize quickly leading to early death. In others, progression is slower, perhaps over 10 years with patients surviving without treatment.

Symptoms

The condition is asymptomatic in its early stages, and often, symptoms do not appear until prostate cancer is far advanced. With spread to the urethra, it may cause symptoms of urinary obstruction that are not unlike benign prostatic hyperplasia (BPH). These include weak or interrupted urine flow, frequent urination especially at night, difficult and/or incomplete urination, pain or burning on urination, and blood in the urine. If spread involves the ureters, the patient may display symptoms of uremia including azotemia, acidosis, and anemia. Skeletal (back, ribs or hip) pain and fractures, spinal cord compression, and the intravascular coagulation syndrome are symptoms of advanced metastatic disease. If rectal obstruction occurs, the individual may experience difficulty in defecation.

There are a number of histologic grading systems proposed to predict the extent of tumor development. None is universally accepted. The American Urological Association system for staging prostate cancer is summarized in Table 1. It divides tumors into four stages of growth. Staging is important because the stage determines the type of therapy indicated. The biologic aggressiveness of the cancer appears to correlate more closely to the degree of cellular differentiation than to the size of the tumor.

Clinical Disease Versus Histologic Prostate Cancer

The prevalence of both clinical and histologic prostate cancer increases with age. After age 50, both incidence and mortality rates from prostate cancer increase at a nearly exponential rate. Prostate cancer increases faster with age than any other major neoplasm. With an aging population, the burden of illness from this cancer will probably continue to escalate in the future.

It is unclear why prostate cancer increases with age much more rapidly than other tumors. Although the clinical incidence varies greatly worldwide, the prevalence of histologic cancer is remarkably similar. Data from autopsy of males around the world demonstrate that 15 to 30 percent of males older than 50 years have histologic evidence of prostate cancer. This increases with age so that by age 80, approximately 60 to 70 percent of males show evidence of histologic carcinoma at autopsy.

It is now generally accepted that development of a fully malignant cancer cell requires multiple malignant genetic events. These include processes that initiate cell transformation and those that promote or encourage the transformation process. If histologic cancer represents a step in development of clinically distinct prostate cancer, then the data suggest that initiation of prostate cancer appears to occur at approximately the same rate independent of the individual's race or nationality.

This concept is supported further by observation that immigrants who move from low-risk areas to the U.S. gradually assume the higher risk of U.S. males. Thus, while the presence of histologic cancer appears to be related to age, other risk factors that increase the development of prostate cancer probably affect promotion of the transformation pathway.

Risk Factors

Family History. It is believed that the incidence of prostate cancer is increased in male relatives of patients with the condition. One study showed a higher incidence of prostate cancer in male relatives of patients with breast cancer. Another reported a familial grouping of prostate cancer in Mormons living in Utah.

These data strongly support the notion that there is increased risk for development of clinical prostate cancer in men who have relatives with clinically evident tumors. In fact, a positive family history is the strongest link to increased risk for prostate cancer.

Thus, the current National Cancer Institute (NCI) prostate cancer screening guideline of a digital rectal examination yearly after age 40 may need to be modified for men with affected family members. The American Cancer Society (ACS) guidelines for screening consist of a yearly digital rectal examination and a PSA test starting at age 50. It is suggested that men with a positive family history of prostate cancer initiate screening at an earlier age, but a specific age is not recommended at this time.

Race. As pointed out earlier, there is broad variation in the incidence of clinical prostate cancer reported in men in different ethnic groups. From both incidence and mortality data, it is clear that the incidence of clinical prostate cancer is low in Asian men and higher in Scandinavian men. Unfortunately, the data are confusing because of differences in life expectancy, diet, socioeconomic status, and methods for reporting.

African-American males have a higher prevalence of prostate cancer than black males in Africa or Asia. In fact, it is the highest rate among 24 countries which keep reasonably reliable mortality data.

African-American males are diagnosed routinely with later-stage disease. Their survival rates are therefore shorter, even when corrected for stage. The five-year survival rates for all stages of prostate cancer are 62 percent for African-American males and 72 percent for white males.

Socioeconomic Factors. Variances in socioeconomic status have been suggested as a cause of the differences in prostate cancer incidence between groups of males. This issue is difficult to resolve since minority populations in some studies represent low socioeconomic groups.

A number of studies have examined the effects of socioeconomic status with both positive and negative results. In one investigation, it was shown that there was no relationship between educational level and prostate cancer incidence. In general, the data support the notion that socioeconomic status is not an important risk factor for development of prostate cancer.

Benign Prostatic Hyperplasia. It is difficult to determine whether BPH is a risk factor for prostate cancer. Both are common diseases in men as they age.

Both diseases are androgen-dependent for growth. BPH arises most often in the central or transitional zone of the prostate, while cancer is most often found in the peripheral zone of the gland.

Occupation. Studies have examined the risk for prostate cancer based upon occupation and physical activity. Results have been mixed.

In a case-controlled study, 75 percent of patients with prostate cancer were farmers compared with 37.5 percent of males in the control group who had BPH. Other studies have not shown significant differences between urban and rural dwellers.

Other occupations that have been associated with a higher incidence of prostate cancer include mechanics, newspaper workers, plumbers, and males in rubber manufacturing industries. These reports have not been confirmed conclusively.

Smoking. A number of studies have correlated cigarette smoking with development of prostate tumors. Relative risks of 1.8 and 2.1 for persons who smoke cigarettes or chew tobacco, respectively, are reported compared with males who do not use tobacco products. Not all studies corroborate this conclusion, however. Studies are also complicated by conflicting data on the effect of cigarette smoking on serum sex hormones. Cigarette smoking probably adds little, if any, to the risk for developing prostate cancer.

Sexual Behavior. Several studies have looked at the history of males with prostate cancer in an effort to determine if there is a relationship between sexual behavior and/or fertility to the development of prostate cancer. Interpreting these studies is difficult because it is often assumed that marriage is synonymous with increased sexual activity, and fertility is usually assessed by the number of children a man admits he has fathered. The relationship, therefore, remains tenuous at best.

Vasectomy. There is a positive relationship between the number of years since vasectomy and risk for prostate cancer. A study of 10,055 males with, and 37,800 males without a vasectomy revealed a relative risk of 1.85 for vasectomized males. This relative risk for prostate cancer increased over time since the procedure was performed with males who had a vasectomy 20 or more years in the past demonstrating a relative risk of 1.89.

In both retrospective and prospective studies, males with BPH have a higher death rate from prostate cancer. However, the reasons for these findings remain unclear. In males under 70 years of age, those with prostate cancer and a history of BPH are more common than in control populations. Other studies have been less conclusive. It is unclear whether there is a true relationship.

Dietary Fat. Epidemiologic data reveal a positive relationship between diet and prostate cancer. This may explain why histologic cancers occur at a similar frequency around the world but clinical incidence is higher in Western societies. The concept that risk for prostate cancer is increased by high dietary fat intake has been debated over the years. It does appear that dietary fat is an important risk factor. A relative risk of 1.6 to 1.9 and odds ratios as high as 3.6 is reported for high unsaturated fat intake.

Other Dietary Factors. Any possible relationship between other dietary factors and prostate cancer is complex. It is difficult to separate the effect of a specific nutrient from other dietary components and associate it with a given cancer. In a study of 14,000 Seventh-Day Adventist males, it was found that increasing consumption of beans, lentils, peas, tomatoes, raisins, dates, and dried fruit significantly decreased the risk for prostate cancer. In general, the results from dietary intake studies support the concept that a high-fiber, low-fat diet may protect males against the development of prostate cancer.

Vitamin A. Several studies have suggested there is augmented risk for prostate cancer development with increased vitamin A intake. Not all studies agree, however. This may be explained by noting that vitamin A in plants (beta-carotene) reportedly reduces risk, contrasted with vitamin A from animal sources which shows evidence of increasing risk.

In Japan and other low-risk areas, the primary source of vitamin A is vegetables. In high-risk countries such as the U.S., the major source of vitamin A is animal fat. Any reported risk for prostate cancer associated with vitamin A intake may actually reflect the higher risk associated with high animal fat intake.

Hormones. The correlation between steroid hormone levels — estrogens, androgens, or adrenal steroids — and development of prostate cancer is poorly understood. It is hypothesized that a low-fat, high-fiber diet affects male sex hormone metabolism by decreasing circulating testosterone. Since testosterone is required for normal prostate epithelium growth, and early prostate cancer has been shown to be endocrine dependent, altered hormone metabolism may play a role in the progression of prostate cancer to its clinically significant stage. The incidence of prostate cancer is very low in eunuchs and castrated males. Higher circulating levels of testosterone in patients with prostate tumors have not been observed consistently. Plasma levels of these hormones do not necessarily reflect intraprostatic hormone levels, however.

In one study, young African-American males had serum testosterone levels that were approximately 15 percent higher than their white counterparts. This difference may help explain the increased risk for prostate cancer in African-American males.

Both African-American and Caucasian males in the U.S. have higher levels of 3-alpha,17-beta-androstenediol glucuronide and androsterone glucuronide than certain other non-American counterparts. Levels of these two androgens are indices of 5-alpha-reductase activity, the prostatic enzyme that converts testosterone to its active metabolite, DHT.

Part 2 of this series will address the role of PSA, treatment modalities, and counseling information.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Prostate Cancer; Part 1: Introduction, Background, and Risk Factors." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members $ 10.00). The completed quiz for this issue must be received by 01/15/02. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-99-001-H01.

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1. The strongest link to an increased risk of prostate cancer that has been found to-date is:
   a. family history of prostate cancer.
   b. personal history of benign prostatic hyperplasia.
   c. family history of breast cancer.
   d. personal history of colon cancer.

2. Which of the following is true?
   a. Prostate cancer occurs more commonly in white males than black males.
   b. It is usually diagnosed before age 50.
   c. It occurs in a higher rate in Japanese males than in Americans.
   d. A definite cause has not been established.

3. Which of the following is true?
   a. Clinical prostate cancer increases with age while the histological form does not.
   b. Prostate cancer incidence increases faster with age than any other major cancer.
   c. Autopsy data show that by age 75, 100 percent of males show evidence of histologic carcinoma.
   d. Development of a fully malignant cancer cell does not require multiple malignant genetic events.

4. All of the following are true about the prostate gland EXCEPT:
   a. it is a firm but elastic organ.
   b. its normal size by age 20 is 20 grams.
   c. it is located at the base of the kidney.
   d. it completely surrounds the proximal urethra.

5. All of the following are components of prostate gland secretions EXCEPT:
   a. prostatic antibacterial factor.
   b. prostatic acid phosphatase.
   c. prostatic-specific antigen (PSA).
   d. spermatazoa.

6. All of the following tissue types are components of the prostate gland EXCEPT:
   a. central tissue.
   b. perianal tissue.
   c. peripheral tissue.
   d. periurethral tissue.

7. The enzyme that catalyzes the conversion of testosterone into DHT is:
   a. 5-alpha reductase.
   b. beta-monoamine oxidase.
   c. 2-carbonic anhydrase.
   d. dopa decarboxylase.

8. All of the following are true EXCEPT:
   a. a low fat, high fiber diet is hypothesized to affect male sex hormone metabolism by decreasing circulating testosterone.
   b. altered hormone metabolism may play a role in the progression of prostate cancer to its clinically significant stage.
   c. the incidence of prostate cancer is very high in eunuchs and castrated males.
   d. plasma levels of male sex hormones do not necessarily reflect intraprostatic hormone levels.

9. According to the American Urological Association classification, tumors extended outside the gland's capsule to tissues around the prostate represent which of the following stages of prostate cancer?
   a. Stage I
   b. Stage II
   c. Stage III
   d. Stage IV

10. Which type of vitamin A reportedly increases prostate cancer risk?
   a. Vitamin A from animal sources
   b. Vitamin A from vegetable sources

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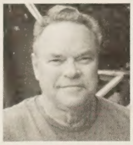
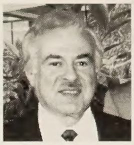

John Martin Stenford
Ketchikan, Alaska

Barbara I. Wunder
Cottonwood, Arizona

John R. Page
Fayetteville, Arkansas

Evelyn Begovich Geisler
Tehachapi, CA

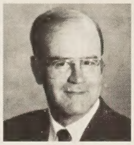
José F. Pérez de Gracia
Bayamón, Puerto Rico


Harold L. Bober
Denver, Colorado

Ernest H. Flesch
Southbury, Connecticut

Gary R. Parosky
Middletown, Delaware

Terrance L. Massey
Quincy, Florida


Bruce L. Broadrick
Dalton, Georgia

Miles T. Nakatsu
Hilo, Hawaii

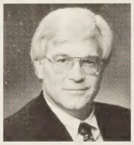
Ed Reddish
Nampa, Idaho

John "Jack" Arkins
Peru, Illinois

Lloyd J. Claybaugh
Evansville, Indiana

Dennis A. Jorgensen
Panora, Iowa

Max M. Heidrick
Beloit, Kansas

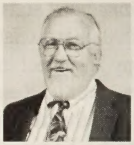

Philip C. Losch
Cynthiana, Kentucky

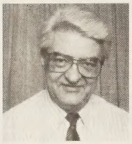
T. Morris Rabb
Monroe, Louisiana

The "Bowl of Hygeia"

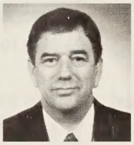
Robert W. Nutting
Oakland, Maine

Lance W. Berkowitz
Baltimore, Maryland

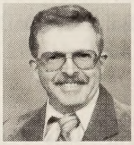

Marion E. Hoar
Haydenville, Massachusetts

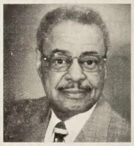

Thomas J. Schaut
Detroit, Michigan

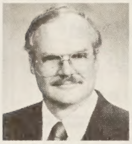
Dale A. Olson
Buffalo, Minnesota


Jerome Marvin Foxworth
Picayune, Mississippi

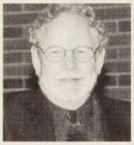
Craig Leonard
Blue Springs, Missouri

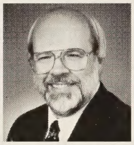

Ron Campbell
Cut Bank, Montana


Maurice L. Russell
Lincoln, Nebraska


John A. Warren
Reno, Nevada

Gary Wingate
Nashua, New Hampshire

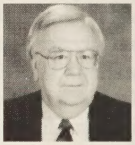

H. Lee Gladstein
Pine Brook, New Jersey

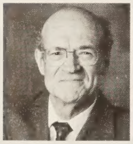

Charles A. Shannon
Roswell, New Mexico

Gary R. Glisson
Nashville, North Carolina

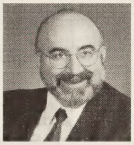
Marvin Tokach
Jamestown, North Dakota

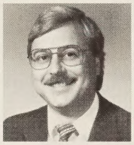
William S. Derry
Van Wert, Ohio

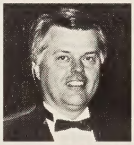

Clifford Meece, Jr.
Sallisaw, Oklahoma

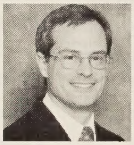

Kenneth D. Boyce
Oakridge, Oregon

William T. Ferri
Murrysville, Pennsylvania

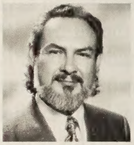

Nat Carolini
Mamaroneck, New York

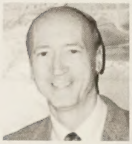

Charles L. Haytaian
Coventry, Rhode Island

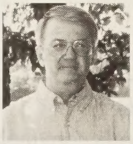

John William Rogers, II
Abbeville, South Carolina


Kevin G. Wurtz
Elk Point, South Dakota

Leonard I. Compton
Bartlett, Tennessee

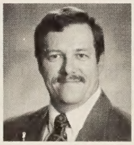

Jose R. Villescas, Jr.
El Paso, Texas


Lamar "J" Hansen
Bountiful, Utah


William J. Brown
Brandon, Vermont

H. David Kafka
Falls Church, Virginia

Richard F. Driskell
University Place, Washington


Roger S. Cole
Wheeling, West Virginia

Thomas R. Roenitz
Sheboygan, Wisconsin

Carol Bivens
Thermopolis, Wyoming

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